

**EFFICACY OF TITANIUM LOCKING MINI PLATES IN THE
MANAGEMENT OF MANDIBULAR FRACTURES : A COMPARATIVE
RANDOMIZED STUDY**

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Declaration

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Abstract

Introduction

Mandibular fractures accounts for 36-70% of all maxillofacial trauma, as the mandible is the only mobile facial jaw bone, with various functions such as mastication, phonation and respiration. Hence the treatment of facial fractures is important for both functional and cosmetic reasons. Champy's ideal lines of osteosynthesis with monocortical mini plate system is the time tested and considered gold standard in the management of mandibular fractures. Transoral placements of miniplates have gained popularity in the last decade. But the quest to improve stability along the fracture fragments has been the need of the hour because of the increased incidence of high velocity road traffic accidents which does not involve normal fracture pattern and in which chances of crush injuries are high, requiring better stability. Conventional screw plating system engages only the bone and may lead to reduced stability by the way of screw loosening which is enhanced by mandibular torsional movements, bony pathologies and age. To overcome this problem newer innovation like locking plates have been developed in which the screws engage both the bone and the plate thus increasing the stability of screws which in turn increases the stability of fracture segments.

Aims & Objectives

The purpose of the study is to evaluate the clinical efficacy of interlocking titanium miniplates by Occlusal stability, post operative infection, postoperative fragment rigidity, wound dehiscence, and the outcomes will be compared with that of conventional titanium miniplates.

Materials & Methods

- **Materials**

- ✓ Titanium 2.0 mm locking miniplates
- ✓ Conventional 2.0 mm miniplates
- ✓ 8 mm and 10 mm self threading titanium screws
- ✓ 8 mm and 10 mm locking screws
- ✓ Titanium bone plating kit

- **Methods**

- ✓ Detailed clinical examination was carried out for all patients and following parameters were noted.
- ✓ Facial asymmetry, occlusion, mouth opening were assessed.
- ✓ Radiographic evaluation of the fractured site.
- ✓ Routine haematological investigations.
- ✓ Medical assessment of the patient by physician and anesthesiologists was done.
- ✓ Informed consent obtained from patient prior to surgery.
- ✓ After the routine clinical and radiological examination protocol the fracture sites were exposed by both intraoral and extra oral approaches with osteosynthesis using 2.0 mm titanium locking plates and screws.
- ✓ Closure was done with 3 - 0 vicryl and 3 - 0 chromic gut sutures.
- ✓ Povidine - Iodine mouthwashes and antibiotic cover (Inj. Cefotaxime - 1gm 12th hourly and Inj. Metronidazole – 500mg 8th hourly) were given preoperatively from the time of admission till 5th post-operative day. The patients were followed up for a period of 6 months in a time interval of 1st week, 1st month, 3rd month and 6th month.

Results

The use of a single locking plate in the treatment of mandibular fractures proved advantageous when compared to the use of conventional miniplate systems. Locking plates showed lesser intra operative time, lesser hardware cost, lesser post operative pain and lesser incidences of post operative complications.

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<p><u>CHAIR PERSON</u></p> <p>Dr. S. Thillainayagam, MDS</p>	<p>This Ethical Committee has undergone the research protocol submitted by Dr. N. Prithivi Sankar, Post Graduate, Department of Oral & Maxillofacial Surgery under the title “ Efficacy Of Titanium Locking Mini Plates In The Management Of Mandibular Fractures : A Comparative Randomized Study “, Reference No : 2015 – MD – Br III – KAR – 07 / APDCH under the guidance of Dr. T. Ramakrishnan for consideration of approval to proceed with this study.</p> <p>This committee has discussed about the materials being involved with the study. The qualification of the investigator, the present norms and recommendations from the Clinical Research Scientific Body and has come to a conclusion that this research protocol fulfills the specific requirements and the committee authorizes the proposal.</p>
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Facial injuries are commonly seen in the trauma patient and may routinely present as a simple laceration to a complex case of pan facial trauma (1). Fractures of the facial skeleton commonly affect the patient with lifelong disfigurement and functional problems, mild to severe psychological impact on the patient and their families and in most of the cases a significant financial burden on the individual (1–3). Documentation, clinical examination, etiology, incidence and patterns of mandibular fractures is essential so as to evaluate our current treatment procedures in order to develop newer techniques for treatment of maxillofacial trauma. Oral & Maxillofacial Surgeons remain indispensable in dealing with cases of maxillofacial trauma (2). The management of maxillofacial trauma still remains a complex procedure and in some complicated cases an enigma due to the intricate anatomy of the human body and all the forces that go into play (4). Following emergency management, the maxillofacial surgeon deals with soft tissue injuries, dentoalveolar injuries and maxillofacial fractures (5). There is a vast difference in the types of maxillofacial trauma which present to health care personnel and this difference occurs because of many factors such as the level of socio economic development, level of education, geographic changes, cultural disparities and other local factors (4,6–8). In developed countries, reported cases of maxillofacial injuries are mostly due to interpersonal violence, but in developing countries like India the etiology of maxillofacial trauma is predominantly due to Road Traffic Accidents (RTA) (4). Epidemiological information about the incidence of maxillofacial trauma is essential to better equip ourselves in treating maxillofacial trauma and for us to better develop advanced treatment methods which are better for both the surgeon and the patient (4). According to a report published by the World Health Organization an estimated 12,00,000 die annually from Road Traffic Accidents worldwide and this estimate has increased substantially with deaths related to Road

Traffic Accidents accounting for 10,00,000 lives in the year 2010 to 12,00,000 lives in the year 2015 (9).

In most cases of maxillofacial trauma the mandible is frequently affected due to its anatomic location and other factors such as the density of the bone (10,11). Taking into consideration that the mandible is the only movable bone of the head and neck region, proper treatment of the fractured mandible is important so as to help the patient return to his / her normal activities. Mandibular fractures may occur as a result due to a variety of injuries but most commonly due to interpersonal violence and road traffic accidents (4). Treatment modalities for mandibular fractures have come a long way from pre historic times to the most commonly used mini plating system along Champy's line of osteosynthesis (12). The first evidence of an attempt to treat a mandibular fracture dates back to the Egyptian era. First documented in 1862, the discovery which came to be known as the Edwin Smith papyrus is the first documented literature on the treatment of mandibular fractures. Though the treatment suggested in the book might not have caused a good outcome, it was the earliest attempt at treating mandibular fractures (13). In the modern era there are various plating techniques which have been used to treat mandibular fractures. Stainless steel was used extensively till it was replaced by titanium. There are variations in the size of the plate, systems which are used and the materials with which the plates are manufactured and they are constantly evolving. The most commonly used type of plating system in the treatment of mandibular fractures is the 2.0 mm Miniplate system (14). Numerous studies have been published both in favor of conventional miniplates and also against them (12,14–17). Some of the commonly encountered problems with the conventional 2.0 mm miniplates were the incidence of infection, loosening of the plates and also the prolonged period of immobilization using Maxillo Mandibular Fixation (18). To overcome these issues locking plates were introduced

in which only one plate was sufficient to successfully reduce a fracture as compared to the usage of two plates in the conventional system (19). Locking plates have proven to be more efficient in terms of lesser incidence of infection and reduced periods of immobilization (17).

Aims

- To evaluate the efficacy of 2.0 mm titanium locking miniplates / screws system in mandibular fractures and compare the results of locking miniplates to that of 2.0 mm conventional miniplates.

Objectives

The purpose of the study is to evaluate the clinical efficacy of locking titanium miniplates and to compare these outcomes with that of conventional miniplates by :

- Pain
- Mouth Opening
- Occlusion
- Paresthesia
- Occlusal stability
- Post-operative infection
- Post-operative fragment rigidity
- Wound dehiscence

A historical perspective of maxillofacial trauma improves the understanding of current techniques and provides the basis for the development of new methods. According to the Arbeitsgemeinschaft für Osteosynthesefragen (AO)/Association for the Study of Internal Fixation (ASIF) principles, the main objective of open reduction and rigid internal fixation in the management of mandibular fractures is to achieve undisturbed healing and immediate restoration of form and function without the adjunctive use of maxillomandibular fixation (MMF) (18).

The recent innovation in treatment is incorporation of general anesthesia, pain management and addition of new biomaterials in the form of titanium miniplates which gave an advantage to the patient towards returning to normal function within days of treatment. The advent of modern biomaterials has changed clinical practice towards plating the bone and early restoration of function.

- **Hippocrates (460 B. C.)** not only devised the technique of reducing a dislocated mandible, but also devised methods of immobilizing a fractured mandible. The ends of the fracture were reduced by hand and the fracture site was immobilized by gold or linen threads tied around the adjacent teeth. He recommended extra oral fixation by strips of Carthaginian leather glued to the skin, the ends of which were tied over the skull (20).
- **Becker (1952)** put forth the basic principles of open reduction of mandibular fractures and the indications and contra indications for open reduction of mandibular fractures. Once the fractures were approached, the fractures were reduced with transosseous wiring which were further immobilized using intermaxillary fixation for a period of time. The scars were very much noticeable. (21).
- **Roberts (1964)** used plates which were composed of cobalt chrome alloys, which were intended for the use of reduction and fixation of metacarpals. They were up to 1 inch or 2.

5 cm in length and they were used to treat a series of mandibular fractures. After the fractured segments were reduced the plates were applied to the outer cortical plate by means of screws which were 7 mm in length and 1.5 mm in diameter. These plates provided sufficient reduction of the fractures segments and good post-operative stability (18).

- **Battersby (1967)** later reviewed a large number of cases over a period of twelve years who had been treated using plates manufactured using the chrome-cobalt-molybdenum alloy manufactured by the Austenal Laboratories of America. He reported that the alloy was inert and did not evoke any significant systemic response. The plates also provided satisfactory reduction of the fractures segments. This treatment protocol proved to be an effective alternative to transosseous wiring, however the patients requires to be put into intermaxillary fixation for a considerable period of time (22).
- **Spießl (1972)** studied rigid internal fixation of the mandible and stated that it's necessary to adapt the plate to the convex surface of the mandible at its lower border. No matter how skillfully the plates were adapted to the lower border there was always a tendency for the upper border and the lingual plate to open with the final tightening of the screws. Ultimately, this caused a distortion of the occlusion and in case of bilateral fractures it caused the opening of fractures on the opposite side. In order to overcome these difficulties, the compression plating system was developed which used a two plate system, one at the lower border and one at the upper border. The compression holes were positioned, one on each side of the fracture (23).
- **Michelet, Deymes & Dessus (1973)** evaluated the use of the mini plates made of cobalt chrome alloys in the treatment of mandibular fractures. They prospectively evaluated 300

cases and reported that though the meta-carpal plates provided sufficient reduction and good post-operative results, they were difficult to adapt. Their popularity faded with time (24).

- **Becker (1974)** described the use of a self-compression plate in the treatment of fractured mandibles. In his study he discovered that the self-compression plate provided stable fixation without rotation. Unlike the compression plates invented by Speissl, both the compression holes were present on the same side of the fracture. Because of the tendency of the upper border to open when compression is applied across the fracture at the lower border, it is necessary to apply a tension band at the level of the alveolus before tightening the screws. An arch bar or a separate plate with screws penetrating the outer cortex only is enough (25).
- **Schilli (1977)** designed a plate with oblique lateral holes which ensured that the compressing force was in part directed towards the upper border so that when the plate was tightened into place there was less tendency for the fracture line to gape. The dynamic compression plate with oblique lateral holes and the additional inlay portion is indicated in the inlay portion in indicated in oblique fractures and when the alveolar process is weak (26).
- **Champy et al (1978)** modified and improvised the technique of mini-plate osteosynthesis in the maxillofacial region. This consisted of mono-cortical juxta-alveolar and sub apical osteosynthesis without compression, inserted through an intra-oral route and supplemented with intermaxillary fixation. They advocated this technique as a routine treatment procedure for mandibular fractures. Taking all the biomechanical forces into consideration they used the photo elastic method and described ideal osteosynthesis lines. The

monocortical screws were sufficient when placed below the roots and either above or below the inferior alveolar canal. At the angle region the plate is fixed on the vestibular flat osseous area located beside the third molar. In case of fractures anterior to mental foramen, in addition to sub apical plate another plate near the lower border of the mandible was fixed. They documented that compression osteosynthesis was not advantageous, as there existed a natural compression along the lower border of the mandible which if excessive could lead to bone necrosis (27).

- **Branemark et al (1983)** used titanium implants in over 400 patients who were treated for edentulousness over a period of 9 years and reported a 91 % percent positive result when using titanium and gold implants for the correction of edentulousness. The high success rate was due to the inert nature of the titanium metal and its resistance to corrosion when it comes with biological fluids (28).
- **Prein J & Kellman RM (1987)** reported the advantages of rigid internal fixation according to the AO/ASIF method with Dynamic Compression Plates (DCP). Results showed good postoperative healing in majority of the patients. The most important advantages of using this technique were found to be the, avoidance of IMF which resulted in early, active, pain free mobilization of the jaws, safe and secure airways without tracheostomies particularly in polytrauma patients and shorter periods of hospitalization. However, the main disadvantages associated with this technique were the bulky nature of the plates , wide extra oral incision, uneven compression by the plate which may lead to infection, psuedoarthrosis and malocclusion and requirement of second surgery for plate removal.
- **Philip L. Maloney et al (1991)** evaluated the validity of a treatment protocol for compound mandibular fractures based on the time of injury to treatment. Fifty-two patients with 71

mandibular fractures were treated in a prospective study. Thirty cases were treated with open reductions with rigid fixation. The remaining 22 patients were treated solely with closed reduction. The results concluded that if the initial treatment is delayed for more than 3 days, any infection at the compound fracture site should first be resolved by MMF and intravenous antibiotics before performing an open reduction (29).

- **J. P. Hayter (1993)** presented a review of literature on the treatment of mandibular fractures with open reduction and rigid internal fixation. Although compression plates were initially used for bone fixation in the maxillofacial region, miniplates replaced them because of advantages like small and easily adaptable plates, mono cortical application, intra-oral approach, functional stability and biomechanical favorability. In miniplate osteosynthesis the mouth opening is also improved and there is no pulmonary deficit when compared to cases with inter maxillary fixation (30).
- **Ellis Edward et al (1996)** evaluated 81 patients with fractures of the mandibular angle that were treated with open reduction and internal fixation using one non compression miniplates with 2.0 mm self-threading screws through a trans-oral approach. None of the patients required post-surgical MMF. Their results suggested that two of the patients required hospitalization and I.V. Antibiotics and one of these patients had a fibrous union that required a bone graft. They concluded that the use of a single miniplate for fractures of angle of mandible is a simple and reliable technique with minimum complications (31).
- **T. Kawai et al (1997)** conducted a study to find out the best time to undertake radiological follow up examinations after mandibular fracture plating through a retrospective study of radiographs. Serial radiographs of 325 fracture sites in 231 patients over a 10 year period were examined and the parameters chosen were osteogenesis and union at the fracture site.

The results showed that radiographic changes are seen with 2-3 months in patients less than 18 years of age and it was 3-4 months for elder patients (32).

- **James W. Sikes et al (1998)** tested the hypothesis that increased resistance to displacement will be obtained when using the locking-head as compared with the number of conventional screws per segment in both fracture and reconstruction models. They concluded that the locking-head screws provided significantly increased resistance to displacement when only 2 screws per segment were used in reconstruction model. When 4 screws per segment were used, there was no significant difference between locking-head and conventional screw types in either model. The effect of bony buttressing was significant and may explain why miniplates often fail in the atrophic mandible but was successful in the fully dentate patients (33).
- **Fordyce et al (1999)** performed a retrospective study of all isolated mandibular fractures which required active management. 115 patients were selected among which 66 patients had fractures reduced manually to obtain reduction without the use of perioperative IMF and 49 patients were treated with conventional IMF. Both groups were similar in severity and type of fracture. The overall results did not show any significant discrepancies between the groups in healing and the study concluded that IMF is not usually necessary to reduce fractures confined to the mandibular bone (34).
- **Potter Jason et al (1999)** evaluated the results of fractures treated by open reduction and internal fixation using one non - compression, thin, malleable miniplate and 1.3 mm self-threading screws placed through a transoral approach in 51 mandibular angle fractures. The plate they used was designed for non-weight bearing fractures of the midface. Their results suggested 15.2 % rate of complication mainly in the form of plate fracture. They concluded

that the use of this small bone plate for fractures of the angle of the mandible provided adequate fixation in most cases but was associated with an unacceptable incidence of plate fracture, hence this plate is not recommended for routine angle fractures (35).

- **Pedro M. Villarreal et al (2000)** in their prospective study evaluated mandibular fracture repair after either maxillo-mandibular fixation (MMF) or rigid Internal Fixation (RIF) using the computer-assisted densitometric image analysis (CADIA) system. Out of 52 patients, 32 were treated by MMF and 20 by RIF. They concluded that the use of RIF results in more rapid bone mineralization than the use of MMF in the first 15 days post operatively while the bone density at 30, 60 and 90 days post operatively did not show significant differences (36).
- **Jose Moreno et al (2000)** conducted a study to identify the complication rates associated with different treatments for mandibular fractures. They compared IMF, 2.0 mm miniplates, 2.4 mm AO plates and 2.7mm AO plates in 245 patients with 386 mandibular fractures. The results showed that the most frequent complication in all the cases was post-surgical infection followed by the other type of fixation postsurgical malocclusion. This study did not show any difference in results with any of the methods used. However, the results concluded that the occurrence of complications is fundamentally related to the severity of the fracture rather than the type of the treatment used (37).
- **Thomas Schug et al (2000)** studied the use of titanium mesh in the treatment of fractures which included extremely atrophic mandibles, discontinuity defects, and marked comminuted fractures. 17 patients with fractures of extremely atrophic mandibles, mandibular discontinuity defects or comminuted fractures were treated with titanium mesh. Union occurred without complication in 70% of fractures treated with titanium mesh. In

20% there were minor complications such as postoperative hematoma. In only one case did infection occur, a more severe complication. They concluded that because of its geometry and the excellent physical and biomechanical properties, titanium mesh helps to achieve better stabilization of complex mandibular fractures than conventional miniplates do. Complications such as infection and nonunion can largely be avoided and bony continuity of the mandible can be restored (38).

- **Hisanori Hirai et al (2001)** obtained specimens from 14 who were diagnosed with mandibular fractures, who had undergone open reduction and internal fixation using titanium miniplates. The specimens were removed with bone along with screws are stained with toluidine blue and were observed under light microscopy. The mean ratio of direct contact between cortical bone and the titanium bone screws was analyzed and was found to be 82.4% for cortical bone and the mean percentage of bone contacts for all screws was 64.4%. The results concluded that titanium bone screws used for mandibular fracture fixation develop almost complete contact with new bone (39).
- **Valfrido Antonio Filho et al (2001)** evaluated the effect of multiple sterilization cycles upon mechanical properties of titanium miniplates (system 2.0, Engimplan). Four groups of fifteen plates were tested on a universal essay machine to verify the resistance to tension, flexion and compression. Group I received no sterilization, whereas Groups II, III, IV underwent one, ten and twenty cycles, respectively. The data was transformed into graphics plotting strength versus deformation. Results concluded that there were no differences in the mechanical properties (traction and compression) of miniplates when submitted up to 20 cycles of sterilization in autoclave. There was significant statistical difference to values of group III in the flexion essay when compared to the other experimental groups (40).

- **Richard H. Haug et al (2002)** conducted a study to determine whether the degree of plate adaptation influences the mechanical behavior of the plate / screw / substrate system. A total of 130 polyurethane mandible replicas were used and were subjected to incisal and molar loading. 2.4mm locking and non-locking reconstruction plates and 2.0mm locking and non-locking plates were adapted on the superior border of the angle region. Load and displacement data was recorded accordingly. The results of the study concluded that the degree of adaptation affected the mechanical behavior of the non-locking system and it did not affect the locking system (41).
- **A.P. Silvia et al (2002)** studied the failure of titanium bone plates used for oral and maxillofacial surgery during use. Microstructural examination of a titanium plate revealed the presence of equiaxed grains and intergranular platelets, which were identified as β phase. Fractographic examination revealed that fracture happened by a transgranular cleavage mechanism associated with secondary intergranular cracking (brittle fracture). Selective attack was observed to occur on the surfaces of the implant. These results indicated that the premature fracture of the miniplate was caused by hydrogen embrittlement (42).
- **Edward Ellis III et al (2002)** examined the use of the 2 mm locking plate/screw system in mandibular surgery. A total of 80 fractures in 59 patients were treated with 2.0 mm locking plate / screw system. There were no intra-operative difficulties associated with their application. Fracture reduction was excellent in all cases. In Locking plates it was unnecessary for the plate to have intimate contact with the underlying bone in all the areas as the screws "lock" to the plate, thus stabilizing the segments. Six patients developed post-surgical infection, only one patient required hospitalization for the treatment of infection;

all others were managed in an outpatient basis. Four patients required removal of their plates for varying reasons. The possible advantages in the use of locking plate/screw system were found to be theoretical but this system provided sound fixation in all cases (43).

- **Yadranko Ducic (2002)** described the use of titanium mesh and hydroxyapatite cement for the treatment of large through-and-through calvarial defects. Twenty consecutive calvarial defects (10 to 156 cm²) that resulted from surgical removal of neoplasms or were secondary to trauma were reviewed retrospectively after reconstruction with titanium mesh and hydroxyapatite cement. There was no evidence of adverse healing, wound infection, or implant exposure or extrusion in any of the patients reviewed. Adequate 3-dimensional aesthetic restoration of calvarial contour was noted in each case. There was evidence of osseous ingrowth into the titanium mesh and hydroxyapatite cement construct in all 3 patients who underwent biopsy. Titanium mesh and hydroxyapatite cement Cranioplasty appears to be a reasonable method for the reconstruction of significant calvarial defects (44).
- **Ralf Gutwald et al (2003)** compared a new internal mini locking system with conventional 2.0 mm mini plates. Standardized osteotomies in the angular region of 16 human cadaver mandibles were fixed with a 6 holed 2.0 mm locking and non-locking plates. Comparison of the different osteosynthesis techniques showed that cases of mini-plate fixation, torsion and gaping of the bone fragments occurred following plate application. The results showed that mini-locking system has better stability than conventional miniplates. The values of loading forces are much less in locking mini plates (45).

- **Marisa Aparecida et al (2003)** reviewed 191 patients with a total of 280 mandibular fractures that were treated with 2.0 mm miniplates. Twenty two fractures developed infection, with an overall incidence of 7.85%. One patient (0.89%) developed inferior alveolar nerve paresthesia, facial asymmetry was observed in 2.67% and incidence of malunion was 1.78%. The overall incidence of complications, including infections, was similar to that of AO fixation (compression plates) (16).
- **Chad P. Collins et al (2004)** compared standard 2.0 mm monocortical plates to 2.0 mm locking plates in the treatment of mandible fractures. Ninety patients with 122 fractures were reviewed. Locking plates were used in 64 fractures and standard plates were placed in 58 fractures. Complication rates were similar in both the groups and it was concluded that mandible fractures treated with 2.0 mm locking plates and standard 2.0 mm plates present similar short-term complication rates (12).
- **Richard J. Shaw et al (2004)** conducted a study to compare complication rates of miniplates versus reconstruction plates in the fixation of vascularized grafts into segmental mandibular defects. A retrospective analysis of 143 consecutive successful microvascular composite flaps performed between 1993 and 2001 was performed. Complications were classified as dehiscence, infection, and plate or bone removal. In the series, 49% of patients received miniplates, and 51% received reconstruction plates. No significant differences in complication rates were found between those grafts fixed with miniplates (27%) and those with reconstruction plates (30%). They concluded that no evidence was found in this study that the increased rigidity offered by reconstruction plates influences the rate of plate or bone removal, infection, or plate exposure. Thus, the decision to use reconstruction or miniplates is not dependent on the rate of plate complications (46).

- **Mario Rocuzzo et al (2004)** evaluated a surgical protocol for vertical ridge augmentation in the maxilla and mandible using autogenous onlay bone graft associated with a titanium mesh. A group of 18 partially edentulous patients, presenting the need for vertical bone augmentation of at least 4 mm, were treated before implant placement. Particulate bone was added and a titanium micro-mesh was used to stabilize and protect the graft. After a mean interval of 4. 6 months, meshes and screws were removed and 37 endosseous implants were successfully placed. Mean vertical bone augmentation obtained was 4. 8mm (range 4–7 mm). The preliminary results suggested that, by using the presented technique, patients can be successfully rehabilitated by means of implant-supported prosthesis 6–7 months after the first surgery, even in case of severely atrophied maxilla (47).
- **Ayman Chritab et al (2005)** conducted a prospective study in 50 mandibular fractures which were treated with 2. 0 mm locking plates placed according to Champy's lines of ideal osteosynthesis. All patients were observed for complications such as soft tissue infections, non-union, mal-union, malocclusion, osteomyelitis, plate fracture and iatrogenic nerve injuries. Results showed 3 complications (6%) which healed uneventfully and primary bone healing has been achieved in 98% of cases. Finally, the study concluded that Locking plate system plus 1 week MMF is a reliable and effective treatment modality for mandibular fractures (48).
- **Hiroshi Mugino et al (2005)** conducted a study to analyze the treatment of fractures of the edentulous mandible and to discuss this method in relation to the mandibular height at the fracture site. Fifteen fracture sites in 11 patients with an edentulous mandible were retrospectively examined, 9 fractures in the mandibular body, 3 in the paramedian region, and 3 in the mandibular angle. Fractures in a mandible measuring more than 10 mm in the

vertical height were treated with one miniplate. Fractures in an extremely atrophic mandible with 10 mm or less were treated using one or two miniplates. The studies concluded that miniplate osteosynthesis is a less invasive treatment and it is suitable for fractures of the atrophic edentulous mandible, except for comminuted or defect fractures. To obtain stable fixation in severely atrophic mandibles, we need to consider the use of two miniplates or a combination with microplates (49).

- **Constantin A. Landes et al (2006)** evaluated the 5-year outcome stability and complications in orthognathic surgery using resorbable versus titanium osteofixation. Twenty-two cleft lip and palate maxillary retrognathia cases were operated on using either poly (70L-lactide-co-30DL-lactide) or titanium miniplate osteofixation. Average operative movement and postoperative instability recorded for maxillary horizontal movement (A-point-Nasion) were 2.5 mm and 2.1 mm for the study group, compared with 6.3 mm and 1.9 mm for the control group. For maxillary vertical movement (ANS-Nasion), measured values were 4.9 mm and 1.3 mm for the study group and 2.3 mm and 0.9 mm for the controls. For mandibular horizontal movement, measured values were 10.7 mm and 2.8 mm for the study group and 1.9 mm and 0.8 mm for the controls. Gonial angle measures were 7.18 mm and 3.58 mm for the study group and 6.78 mm and 3.18 mm for the controls. They concluded horizontal maxillary stability appeared inferior to vertical stability, but mandibular stability was more reliable. Because groups were not matched for magnitude or direction of movement, the results of this study are preliminary and should be interpreted cautiously (50).
- **Michael. A. Miranda et al (2007)** reviewed the usage of innovative locking plate for the purpose of osteosynthesis in osteoporotic bone for long bones. Osteoporosis is a relative

contraindication for internal fixation because of poor results. In osteoporotic bone the quality of bone becomes the prime determinant of screw holding power in normal conventional non locking screws. In summary, locking plate technology has been shown to improve the anchorage of plates in osteoporotic fractures, but its application is technique sensitive (51).

- **Domenick P. Coletti et al (2007)** used a red oak model and compared the locking mechanism of tapered design to the more well established threaded design by measuring the seating torque, plate flexure, fracture displacement, screw stripping, and screw head deformation of the various systems. Observation and comparison of the hardware failures of the two different plate-screw designs were the goal of the study. The results showed that there was less screw stripping and higher seating torque in the tapered systems when compared with threaded systems which provided an effective locking mechanism. Plate flexure was an unanticipated finding in all designs, with a higher incidence noted in a tapered design. Fractured displacement should theoretically be eliminated when using a locking plate. Interestingly, there was no statistical difference between the two designs (52).
- **C. N. Elias et al (2008)** presented a review of literature on the composition of titanium. Titanium with 6% aluminium, 4% vanadium has long been a main medical titanium alloy. It is categorized by American society of testing materials (ASTM) as grade V titanium, which is used for bone plates and screws. Mechanical properties of grade V titanium are : yield strength (Pa)-795, tensile strength (Mpa)- 860, percentage of elongation-10%, modulus of elasticity (Gpa)-114-1209 (53).

- **Alparslan Esen et al (2008)** conducted an experimental study on sheep hemimandibles to compare the stability of titanium and absorbable plate and screw fixation system using 3 different plating techniques (single titanium plate, single absorbable plate, double absorbable plates). The study demonstrated that the titanium plate and screw fixation system had greater resistance to occlusal loads than absorbable plate and screw systems. In addition a second absorbable plate orientation provides a more favorable biomechanical behavior than a single absorbable plate system (54).
- **Nayak et al (2008)** analyzed the benefit of primary reconstruction of depressed fractures and compared the various options available today. The various techniques adopted by the author like simple elevation, apposition by nylon suture; or rigid fixation by titanium and absorbable mini plate were undertaken. Twenty two patients were included in this study out of which ten were male and ten were female. Eighteen (56%) cases underwent titanium miniplate fixation and eleven (34%) apposition using nylon sutures. In two cases simple elevation of fracture segments was carried out and in one fixation with absorbable (Poly-L- lactide) miniplate, was performed. Cosmetic deformity correction to acceptable level was achieved better with miniplates. Primary reconstruction of depressed fracture segment should be attempted whenever possible. The biodegradable miniplates are implant of choice, but the titanium mini plates are cost effective and a better option when compared to any other available measures (55).
- **Charles. H. C et al (2009)** conducted a study in 9 cases with atrophic nonunion of humoral diaphysis treated with locking plate fixation and recombinant human bone morphogenetic proteins. All cases were diagnosed with atrophic nonunion prior to surgery. All patients were treated with locking plate system. Locking plates function as “internal fixators” which

allow for stable fixation without directly compressing the bone. The results showed that this technique is useful and reliable in patients with atrophic bone or osteopenia (56).

- **J. O ‘Connell et al (2009)** performed a 10 year retrospective study to evaluate the indications for the removal of titanium miniplates following osteosynthesis in maxillofacial trauma and orthognathic surgery. The following variables were recorded : patient gender and age, number of plates inserted, indications for plate placement, location of plates, number and location of plates removed, indications for plate removal, time between insertion and removal, medical co-morbidities, and the follow-up period. During the 10 years of the study, 1247 titanium miniplates were placed in 535 patients. A total of 32 (3%) plates were removed from 30 patients. Superficial infection accounted for 41% of all plates removed. All complications were minor and most plates were removed within the first year of insertion. A low removal rate of 3% suggests that the routine removal of asymptomatic titanium miniplates is not indicated (57).
- **Allan S Herford et al (2009)** examined the use of the locking reconstruction bone plate/screw system for fractures of the mandible or continuity defects during an 18 month period. 102 locking bone plates were placed in 84 patients. There were no cases of malocclusion or difficulties encountered in using the plate/screw system. Loss of fixation was seen in only one patient. The use of a locking plate/screw system was found to be simple, and it offers advantages over conventional bone plates by not requiring the plate to be compressed to the bone to provide stability (58).
- **Rudolf Seemann et al (2009)** conducted a prospective randomized multicenter study for the comparison of osteosynthesis failure rates of locking and non-locking plates in the treatment of mandibular condyle fractures. Locking plates were applied in a total of 72

fractures and non-locking systems were used in 74 patients. Data were acquired during 3 distinct periods 1. Peri-operatively; 2. 5 - 7 weeks after surgery; 3. 5-7 months after surgery. In 142 condyles excellent healing was seen (overall success rate of 97.3%), 4 cases of osteosynthesis failure rates were observed (failure rate of 2.7%). Plate fracture occurred twice in the locking and once in the once in non-locking group. Screw loosening occurred twice exclusively in the nonlocking group. Their results concluded that the Medartis Trilock locking and Medartis non locking condylar plates show equivalent complication rates (15).

- **Baohui Ji et al (2010)** evaluated the stress distribution and stress shielding effect of titanium miniplates used for the treatment of symphyseal fractures using the finite element analysis. The results showed that ratio of lower miniplates in technique 2 (reduction with 2 miniplates) were much higher than upper miniplates and the mini plates in technique 1 (reduction with a single miniplate), and the value of lower miniplates gained a maximum value of 83.34% during left unilateral molar clenching. The study demonstrated that miniplates stress distribution and stress shielding effect ratio were affected not only by the way in which the mandible was loaded but also by the number of miniplates fixing the fracture (59).
- **Samrat Sabhlok et al (2010)** evaluated the efficacy and stability of 2.0 mm titanium plates in treatment of mandibular angle fractures. 17 patients were treated by ORIF with 2.0mm titanium plates. Operative handling of the plate and clinical stability were qualitatively analyzed. The 2.0 mm plate showed good intra-operative handling and adequate clinical stability with follow up of 6 months showing good soft tissue healing. They concluded that a single 2.0mm plate provides easy handling and adequate occlusal stability in the post-

operative phase as compared to the traditional 2.5 mm plate without post-operative MMF (60).

- **Sauerbier et al (2010)** evaluated the use of a 2.0-mm locking plate system in mandibular surgery. 53 patients (42 male, 11 female) with a total of 56 mandibular fractures were treated with a 2.0 mm mini-locking-plate system and retrospectively examined. Gender, age, cause of fractures, surgical access, classification of fractures, osteosynthesis, postsurgical findings and complications were evaluated. The use of a 2.0-mm locking plate system with its advantages of improved handling characteristics, increased stability, shorter surgical time and the preservation of bony perfusion is a viable alternative to conventional miniplates in the management of mandibular fractures (61).
- **Dogan Dolanmaz et al (2010)** evaluated a study in which six unembalmed adult sheep mandibles were stripped of all soft tissues and sectioned at the midline. Each side had a sagittal split ramus osteotomy (SSRO) and was advanced by 5 mm. Six of the hemi mandibles were fixed with four-hole extended titanium miniplates and titanium screws, and the other six were fixed with four-hole extended absorbable plates and absorbable screws. All specimens were mounted in a servohydraulic testing unit, and a range of forces (0—140 N) was applied. Displacement of each proximal segment was recorded at 10 N increments from 0 to 140 N. Values for the two groups were compared using the Mann—Whitney *U*-test, and significant differences in displacement were seen only at loads between 10 and 50 N. The results indicate that when absorbable miniplates are used intermaxillary fixation may be necessary to stabilise the bony fragments in the early postoperative period (62).

- **Paolo Scolozzi et al (2010)** prospectively evaluated the use of a single Arbeitsgemeinschaft für Osteosynthesefragen (AO) 2.0-mm locking reconstruction plate for linear noncomminuted mandibular fractures without the use of a second plate. They analyzed the clinical and radiologic data of 45 patients with 74 fractures (21 single fractures, 22 double fractures, and 2 triple fractures). Fracture locations were the symphysis (n - 35, 47.3%), body (n - 15, 20.3%), and angle (n - 24, 32.4%). All patients had satisfactory fracture reduction and a successful treatment outcome without major complications. Ten patients (22.2%) developed minor complications. The results has demonstrated that treating linear noncomminuted mandibular fractures with a single AO 2.0-mm locking reconstruction plates is associated with no major complications and sound bone healing in all patients (18).
- **Paulo Domingo et al (2010)** conducted an in vitro study to access the biomechanical stability of 9 different osteosynthesis methods which included various combinations of locking and non-locking plate / screw systems after sagittal-split ramus osteotomies in 45 polyurethane hemi mandibles. All 9 combinations were tested on a universal testing machine with increasing compressive loads until a 3mm displacement was observed. The results concluded that there was no statistically significant difference of stability between locking miniplates and non-locking mini plates but locking miniplates presented a better performance in bone fixation in all groups (63).
- **Verma A et al (2011)** conducted a clinical study to evaluate the efficacy of locking plates and conventional mini plates in 43 mandibular fracture patients. 22 patients were treated with 2 mm conventional mini plates (Group A) and 21 patients with 2 mm locking mini plates (Group B). All the patients were evaluated for complications. Group B showed a 4.7

% complication rate in when compared with 13.6% Group A. The study supports the concept of higher stability of the locking plates over non-locking plates (64).

- **Chandan Prabhakar et al (2011)** evaluated the efficacy of locking miniplates/screw system in the treatment of mandibular fractures without maxillomandibular fixation. He concluded that the locking miniplates system was found to be reliable and effective in management of mandibular fractures without postoperative intermaxillary fixation (65).
- **Shivani Jain et al (2011)** compared the clinical and radiological outcomes of open treatment of mandibular fractures using titanium miniplates or intraosseous wires. The study also aimed to find out whether internal fixation with titanium miniplates can effectively reduce the period of maxillomandibular fixation (MMF). 40 patients who sustained mandibular fractures were divided into 2 groups. Group I included 20 patients who were treated using intraosseous wires and post-operative MMF for 4 weeks. Group II A included 10 patients who were treated using titanium miniplates and post-operative MMF for 1 week and Group II B comprised of 10 patients who were treated using titanium miniplates and no post-operative. MMF. Results concluded that the use of bone plates assures early restoration of normal form and function as compared with the use of intraosseous wiring which was associated with extended period of MMF (66).
- **Deepak et al (2011)** studied the versatile nature and the biocompatibility of the titanium material and determined the usefulness of titanium mini plates over the stainless steel plates in the management of fractures of mandible. In a total of 34 patients the T-test revealed a significant difference in the average time taken for adaptation and plating of the 2 system of plates. The average time taken for stainless steel plate was 6.82 minutes and for that of titanium was 3.64 minutes. The test for comparison of infection rate showed that 20% of

the patients treated with stainless steel plates and screws had local infection while the success rate for titanium plates was 100%. 20% of cases treated with titanium system encountered the complication of shearing and fracture of the titanium screw head while fitting the screw. Wound dehiscence in case of stainless steel bone plates was noted in one out of ten patients (10%) while in the group treated with titanium plates it was 0%. They concluded that titanium plates were found to be very ideal in the management of mandibular fractures. Titanium plates were more biocompatible when compared to stainless steel plates as evidenced by the rate of infection. In all cases the plates were found to be rigid, stable and satisfactory for use in the facial skeleton. Titanium plates being more malleable were easily adapted to the varying contours of the mandible which clinically translated into reduced time required for plating (67).

- **Singh et al (2011)** conducted a prospective controlled study to evaluate the efficacy of a 2.0 mm locking plate / screw system compared with a 2.0 mm non locking plate / screw system in mandibular fractures. Patients were evaluated 12 weeks post operatively. Complications were assessed according to the type of plate used and the site of the fracture. The study concluded that the number of patients requiring post operative inter maxillary fixation was significantly higher in the control group. The overall statistical analysis showed no significant changes in the complication rates when both the groups were compared (17).
- **Laxmi Gandhi et al (2012)** evaluated numerous advances in microsurgical technique; plating technology and instrumentation, in technique continue to improve the functional and aesthetic outcomes of oromandibular reconstruction. The latest innovations are self-drilling, self-tapping screws, locking miniplates these screws offer the prospect of less

instrumentation and faster application. Preclinical testing has shown them to be substantially more retentive in cancellous bone, a significant advance in cancellous block bone grafting. Locking 2.0 mm miniplates utilize double threaded screws which both lock to the bone and the plate creating a mini-internal fixator and are designed for midface application in the repair of fractures, osteotomies and defects. Locking plates / screws system proved to be more rigid, reliable and increased stability than conventional Plates / screws system, thereby reducing the need and duration of IMF. Shorter surgical time and preservation of bony perfusion is a viable alternative to conventional miniplates in the management of mandibular fractures (68).

- **Babu S. Parmar et al (2014)** prospectively evaluated the use of Arbeitsgemeinschaft für Osteosynthesefragen (AO) 2.0 mm locking reconstruction plate for linear non-comminuted mandibular fractures without the use of a second plate. The study has demonstrated that treating linear non-comminuted mandibular fractures with a single AO 2.0 mm locking reconstruction plate provides excellent stability at the fracture site which in turn leads to sound bone healing and early functional rehabilitation (19).
- **Balakrishnan et al (2014)** studied the use of three dimensional titanium miniplates to stabilize mandibular fractures. The three dimensional plating system is based (Farmand 1993) on the principle of obtaining support through geometrically stable in the three-dimensions of the fracture site since it offers good resistance against torque forces. The study was conducted in six patients having fractured mandible with a total no of twelve fractures sites. All the patients were treated with locking 3D titanium miniplates. During the course of the study the three - dimensional titanium miniplates were found to be standard in profile, strong yet malleable, facilitating reduction and stabilization at both the

superior and inferior borders giving 3 - dimensional stability at fracture site. Results concluded that 3-D titanium mini plate system may be considered as a viable treatment option for mandibular fracture management (42).

- **Chrcanovic (2014)** conducted a meta analysis to determine whether there was a significant difference in the outcome between locking plates and non locking plates. After a thorough search 10 studies were included in the meta analysis and the study revealed that there was no statistic difference on post operative infection, malocclusion, hardware failure, hardware removal, wound dehiscence. However all the outcomes were in favor of the locking plates, proving that locking plates are a better treatment modality for the treatment of mandibular fractures (69).

This is a prospective study conducted on 30 patients who were clinically and radiographically diagnosed with mandibular fractures, from 2015 - 2017. The cases were planned for Open Reduction & Internal Fixation ↓ GA (ORIF) in the Department of Oral and Maxillofacial Surgery, Adhiparasakthi dental college and hospital, Melmaruvathur.

IRB Approval:

Before the start of the study, the methodology was presented to the IRB and approval was obtained. (2015 – MD – Br III – KAR – 07 / APDCH)

Grouping of Samples

Sampling Procedure	Patients reporting to the Department of Oral & Maxillofacial Surgery, Adhiparasakthi Dental College & Hospital with Mandibular Fractures
No of Groups	Two Control group (Group 1) Experimental group (Group 2)
Sample Size	15

Table 1 – Grouping of Samples

Patient Selection

Patients reporting to The Department of Oral & Maxillofacial Surgery, Adhiparasakthi Dental College & Hospital, Melmaruvathur 603 319, Tamilnadu with mandibular fractures will be included in this study.

Inclusion Criteria

- Patients between ages 18-60 years diagnosed with mandibular fractures
- Dentate patients
- Both the sexes will be included
- Keys of occlusion to be present
- Patients comes under ASA (American Society of Anaesthesiologists) Type – I & II

Exclusion Criteria

- Polytrauma Patients
- ASA III & IV
- Paediatric Patients
- Edentulous Patients
- Fracture with mal-union/non-union/infected sites
- Condylar & Coronoid Fractures

Materials

- 2.0 mm titanium locking miniplates
- 8 mm and 10 mm locking titanium screws.
- 2.0 mm conventional miniplates
- 8 mm and 10 mm titanium screws
- Titanium bone plating kit

Methodology

The study subjects were first monitored for any vital changes and any underlying medical conditions. If there were any abnormalities in the vitals, they were first addressed before any definitive management of the fractures could be addressed. In the case of presence of any active haemorrhage, the haemorrhage was first addressed. Detailed clinical examination was carried out both by inspection and palpation for all patients and the following parameters were noted.

- Facial asymmetry, occlusion, mouth opening, pain were assessed.
- Radiographic evaluation of the fractured site.

Study subjects are divided into two groups.

- Group A - ORIF with conventional 2.0 mm miniplates
- Group B - ORIF with titanium interlocking 2.0 mm miniplates

Following clinical and radiological diagnosis the following were done

- Placement of Erich's arch bar ↓ LA.
- Routine haematological investigations.
- Medical assessment of the patient by physician and anesthesiologists was done.
- Informed consent obtained from patient prior to surgery.

Operative Procedure

- Patient intubated using Naso Endo Tracheal Intubation.
- Painting of the surgical site using 5 % Povidone Iodine.
- Administration of 2 % Lignocaine with 1 : 2,00,000 Adrenaline using Local Infiltration at the site of the fracture.
- Incision marking.
- Placement of Surgical Incision using electrocautery.

- Layer by layer dissection.
- Exposure of fracture site & fracture reduction
- Maxillomandibular fixation placed.
- Fixation of fractured segments using conventional miniplates or locking plates.
- Irrigation of the surgical site with Normal Saline & Metronidazole.
- Layer by layer closure done using 3 – 0 vicryl in case of intra oral approach or 4 – 0 ethilon in case of extra oral approach.
- Extubation of the patient.

Post Operative Care

- Control Group – MMF was placed for a period of three weeks.
- Experimental Group – MMF was not placed.
- Patients were administered 1 gram of Cefotaxime 12th hourly and 500 mg of Metronidazole 8th hourly intravenously for three days.
- Following discharge, post operative instructions were given to the patient.
- Patients were advised to take 200 mg of Cefotaxime and 400 mg of Metronidazole orally for a period of five days.

Post Operative Evaluation

Each group was divided into six comparative stages

- Pre Operative
- Immediate post-operative state
- First week
- First month
- Third month

-
- Sixth month

Evaluation of Parameters

Pain :	Pain was evaluated using a 10 point VAS scale.
Mouth Opening :	Maximal mouth opening was evaluated by measuring the inter incisal distance
Infection :	Presence of pus discharge from the surgical wound was indicative of infection.
Wound Dehiscence :	The wound healing was evaluated based on the presence or absence of wound gaping
Segmental Mobility :	Segmental mobility was evaluated by bimanual palpation
Occlusion :	Pre operative and post operative occlusion was evaluated.
Plate Exposure :	Surgical site was evaluated for the presence or absence of plate exposure
Paresthesia	Nerve paresthesia was evaluated using a pin prick test
Assessment of Reduction :	The reduction of the fractured segments was evaluated by the surgeon, radiographically

Table 2 – Evaluation of Parameters

A total of 30 patients, who met the inclusion criteria, were included and treated for mandibular fractures in the Department of Oral & Maxillofacial Surgery, Adhiparasakthi Dental College & Hospital, in this study. All the cases were diagnosed to have mandibular fractures after thorough clinical and radiological examination. 15 patients were allocated to Group A (Experimental Group) and 15 patients were allocated to Group B (Control Group). After informed consent was obtained all pre-operative parameters were measured. After completion of the hematological investigations and the radiological investigations, the case was operated and during the post-operative period all the parameters were again measured. The data collected were compiled using Microsoft Excel 2016 and was subjected to Statistical Analytical Tests, performed using IBM Corporation Statistical Package for Social Science, Version 22. 0 (Armonk, NY).

Fisher's Exact Test, Mann Whitney U Test & Paired T Test were used to calculate the statistical difference between the control and the experimental group. In all the tests conducted, a P value less than 0.05 was regarded as statistically significant. None of the patients reported any life threatening adverse events. A total of 30 patients were included in this study and they were split into two groups.

Control Group	-	2. 0 mm Conventional Miniplates
Experimental Group	-	2. 0 mm Locking Miniplates

1. Sex

In the control group, out of the 15 patients who were treated 14 were male (94 %) and 1 was female (6 %). In the experimental group, out of the 15 patients who were treated all 15 were male (100 %).

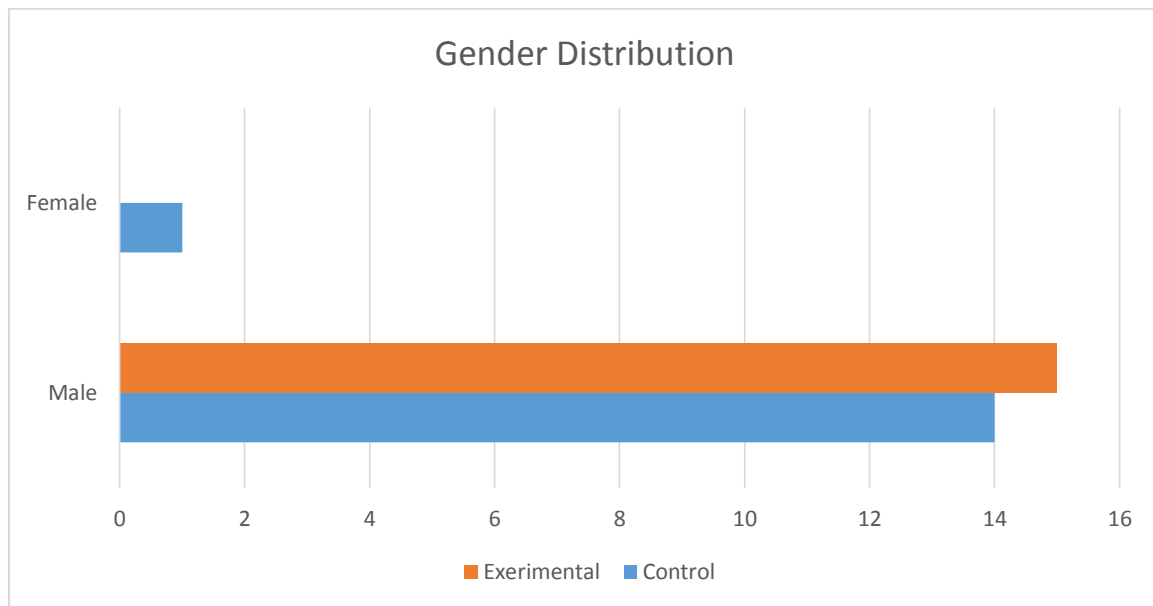


Chart 1 – Gender Distribution

2. Age

This study included patients between the age of 16 and 80. When the age distribution was analyzed the patients were grouped into five categories for easy analysis. They were divided into five groups namely 16 – 20 Years, 21 – 30 Years, 31 – 40 Years, 41 – 50 Years, 51 – 60 Years.

When the age distribution was studied it was discovered that in the control group 26.7 % of the participants were in the age group of 16 – 20 years ($n = 4$), 33.3 % of the participants were in the age group of 21 – 30 years ($n = 5$), 13.3 % of the participants were in the 31 – 40 age group ($n = 2$), 20 % of the participants were in the age group 41 – 50 ($n = 3$) and 6.7 % of the participants

belonged to the 51 – 60 age group (n=1). In the experimental group 6.7 % of the participants were in the age group of 16 – 20 years (n = 1), 40 % of the participants were in the age group of 21 – 30 years (n = 6), 33.3 % of the participants were in the 31 – 40 age group (n = 5), 6. 7 % of the participants were in the age group 41 – 50 (n = 1) and 13. 3 % of the participants belonged to the 51 – 60 age group (n =2).

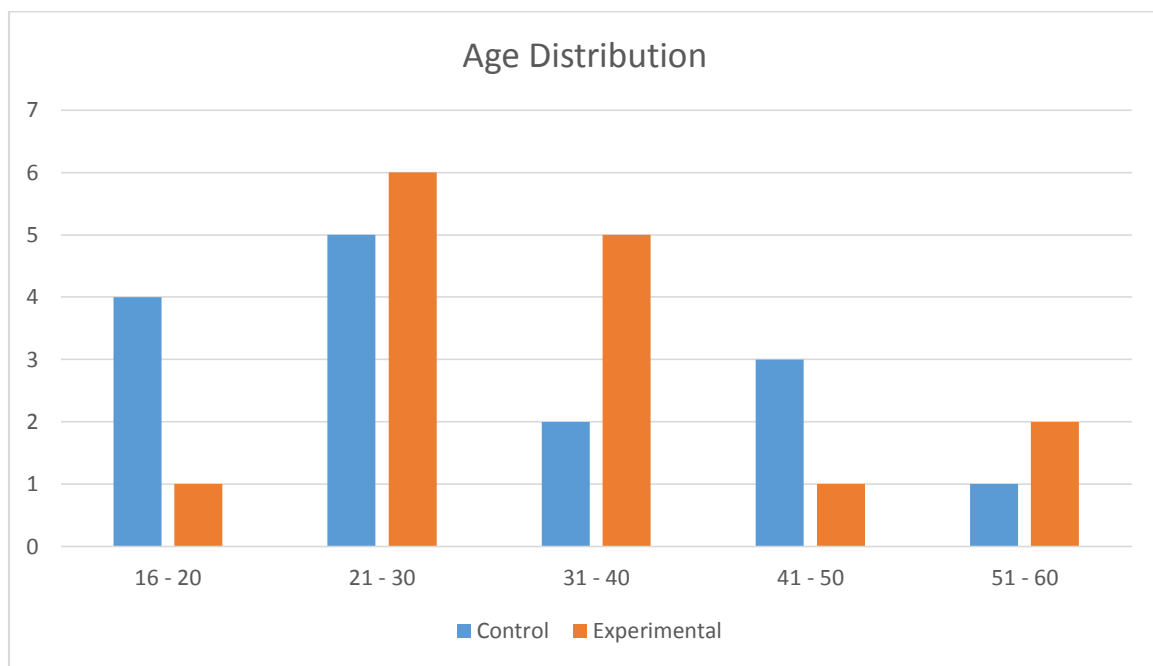


Chart 2 – Age Distribution

The mean age of the participants in the control group was 30. 41 years with a standard deviation of 13. 30 years. The mean age of the participants in the experimental group was 34. 21 years with a standard deviation of 15. 13 years.

3. Etiology of Injury

Mandibular trauma can have varied etiology and in this particular study the etiology of the trauma was also elicited. In the control group, 85.5 % cases reported with mandibular fractures due to a road traffic accident (n = 13) and 14. 5 % of cases reported with mandibular fractures

reported because of domestic violence (n = 2). In the experimental group, 86. 7 % of cases were due to road traffic accidents (n = 13), 6. 7 % of cases reported because of an accidental fall (n = 1) and 6. 7 % of cases reported because of domestic violence (n=1). The results obtained from this particular study showed that road traffic accidents were a leading cause of mandibular fractures.

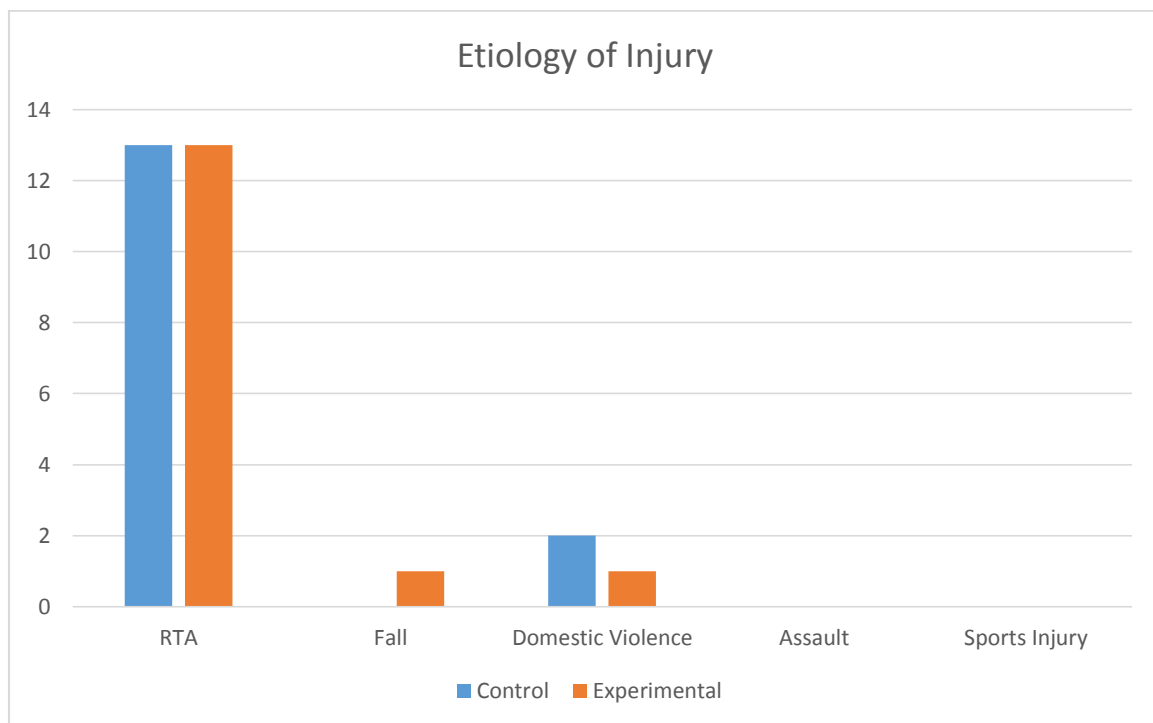


Chart 3 – Etiology of Injury

4. Influence of Alcohol

In the control group, cases who reported with mandibular fractures as a result of a road traffic accident were examined further to determine whether or not the individual was under the influence of alcohol. In the control group, 13 out of 15 mandibular fractures were due to a road traffic accident, out of which 46. 7 % cases were under the influence of alcohol (n = 6) and 53. 3 % of cases were not under the influence of alcohol (n = 7). In the experimental group, 13 mandibular fractures were caused due to road traffic accidents. In these cases 66. 7 % of cases

were under the influence of alcohol ($n = 10$) and 33.3 % of cases were not under the influence of alcohol. A strong predilection for consumption of alcohol and road traffic accidents was noted from the findings of this study.

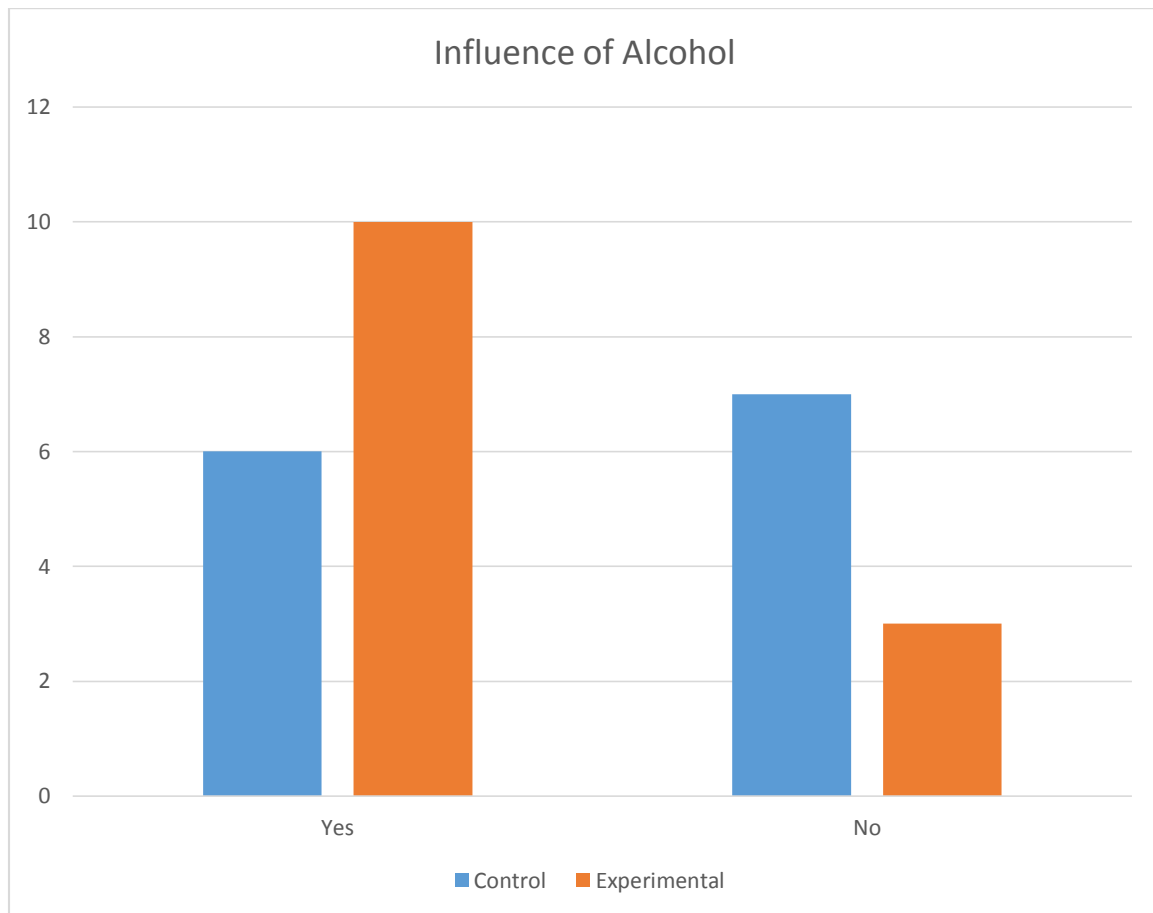


Chart 4 – Influence of Alcohol

5. Usage of Helmet

In cases of road traffic accidents which were included in this prospective study, whether or not the patients were wearing a helmet at the time of the accident was noted. Out of the 13 cases of road traffic accidents in the control group only 9.7 % of the cases wore a helmet ($n = 1$) whereas 90.3 % of cases did not wear a helmet ($n = 12$). In the experimental group 100 % of the mandibular

fractures due to road traffic accidents were not using a helmet at the time of the accident (n = 13).

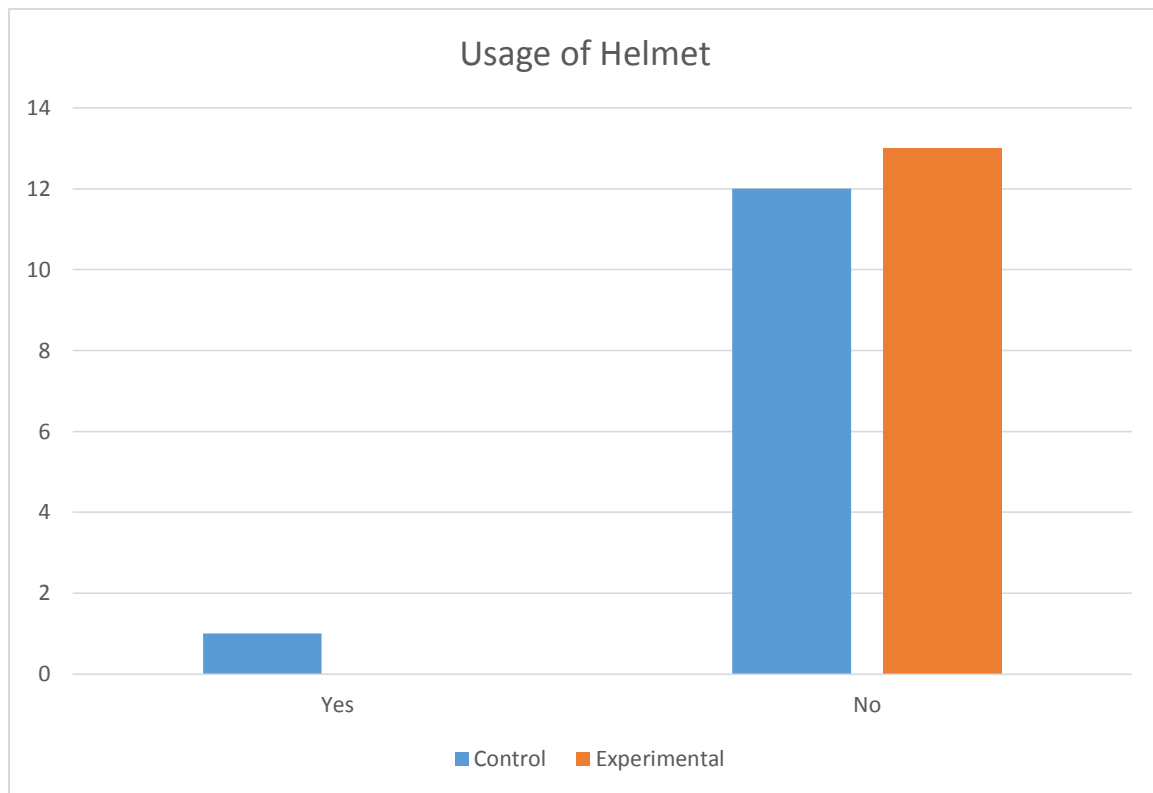


Chart 5 – Usage of Helmet

6. Time for Injury to Hospitalization

The time taken for the individual to report to the hospital following the injury was noted in this study. In the control group, 33.3 % of cases reported within 24 hours of the accident (n = 5), 46.7 % of the patients reported within 24 – 48 hours (n = 7), 13.3 % of patients reported between 48 – 72 hours after the accident (n = 2) and 6.7 % of patients reported later than 96 hours (n = 1). In the experimental group 26.7 % of the study population reported to the Department of Oral & Maxillofacial Surgery within the first twenty four hours of the accident (n = 4), 60 % of the patients reported to the hospital between 24 – 48 hours (n = 9), 6.7 % of the patients reported between 48 – 72 hours (n = 1) and 6.7 % of the patients reported between 72 – 96 hours (n = 1).

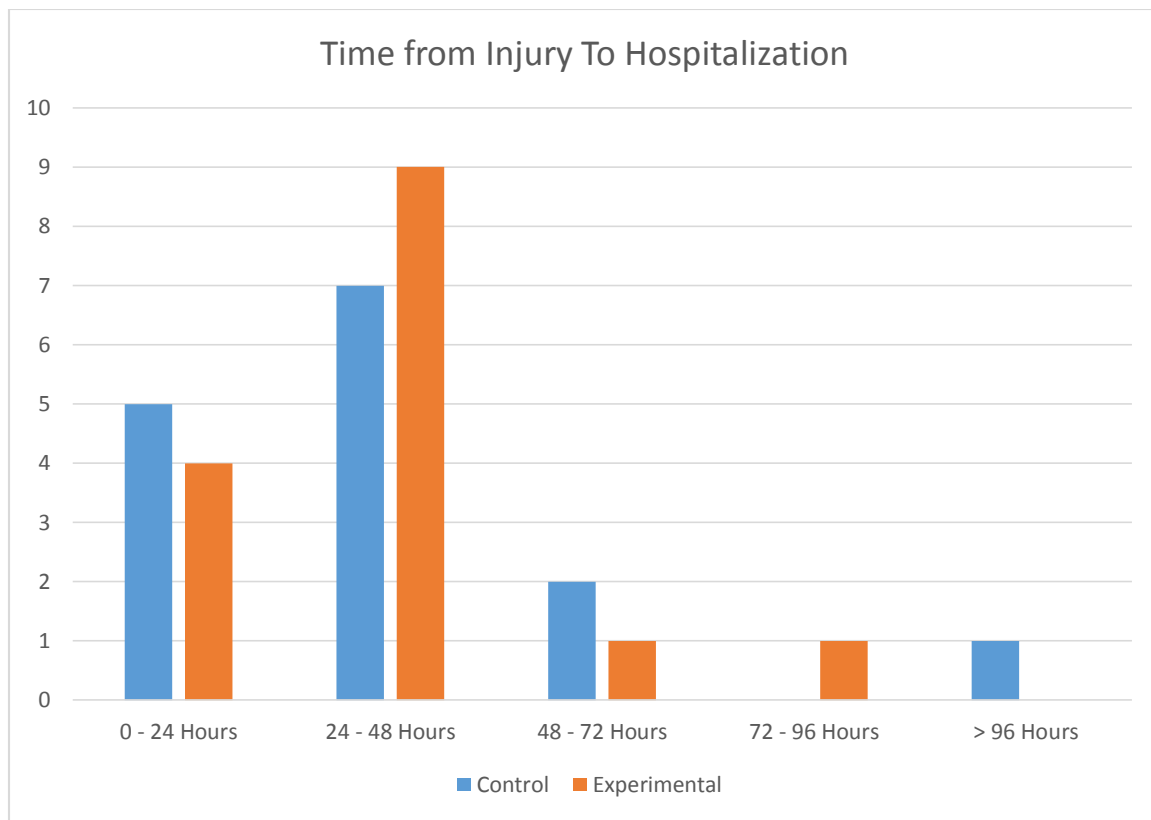


Chart 6 – Time from Injury to Hospitalization

7. Location of Fracture Site

In both groups the location of the fracture site was noted according to Dingman & Natvig's Classification. In the Control Group, 53.3 % of fractures occurred at the Parasymphysis region (n = 8), 13.3 % of the fractures occurred at the body region (n = 2). 33.3 % of fractures occurred at the region of the angle (n = 5). In the experimental group, 6.7 % of fractures occurred at the symphysis region (n = 1), 60 % of fractures occurred at the site of the parasymphysis (n = 9), 26.7 % of the cases at the region of the body of the mandible (n = 4) and 6.7 % of the fractures occurred at the region of the angle (n = 1). According to the findings from this study the most common site of the fracture was the Parasymphysis of the mandible. Fractures of the Parasymphysis also presented with fractures of the condyle of the mandible.

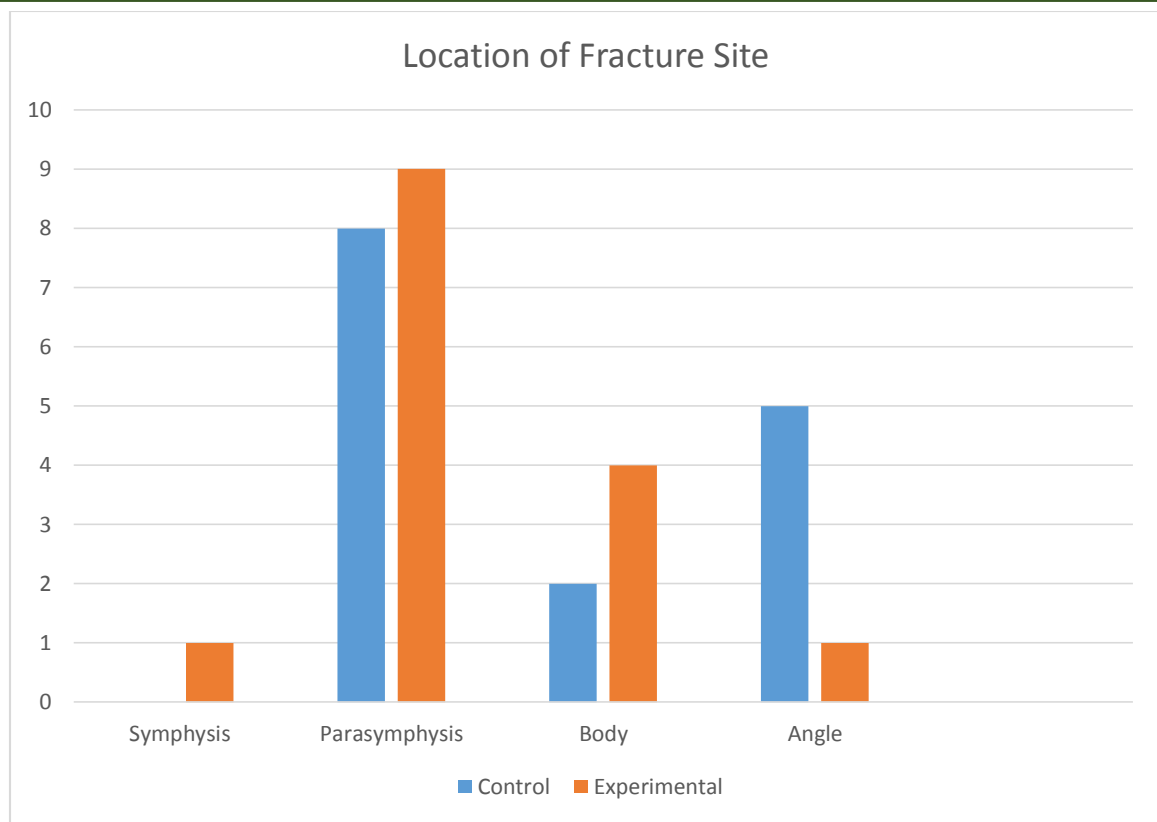
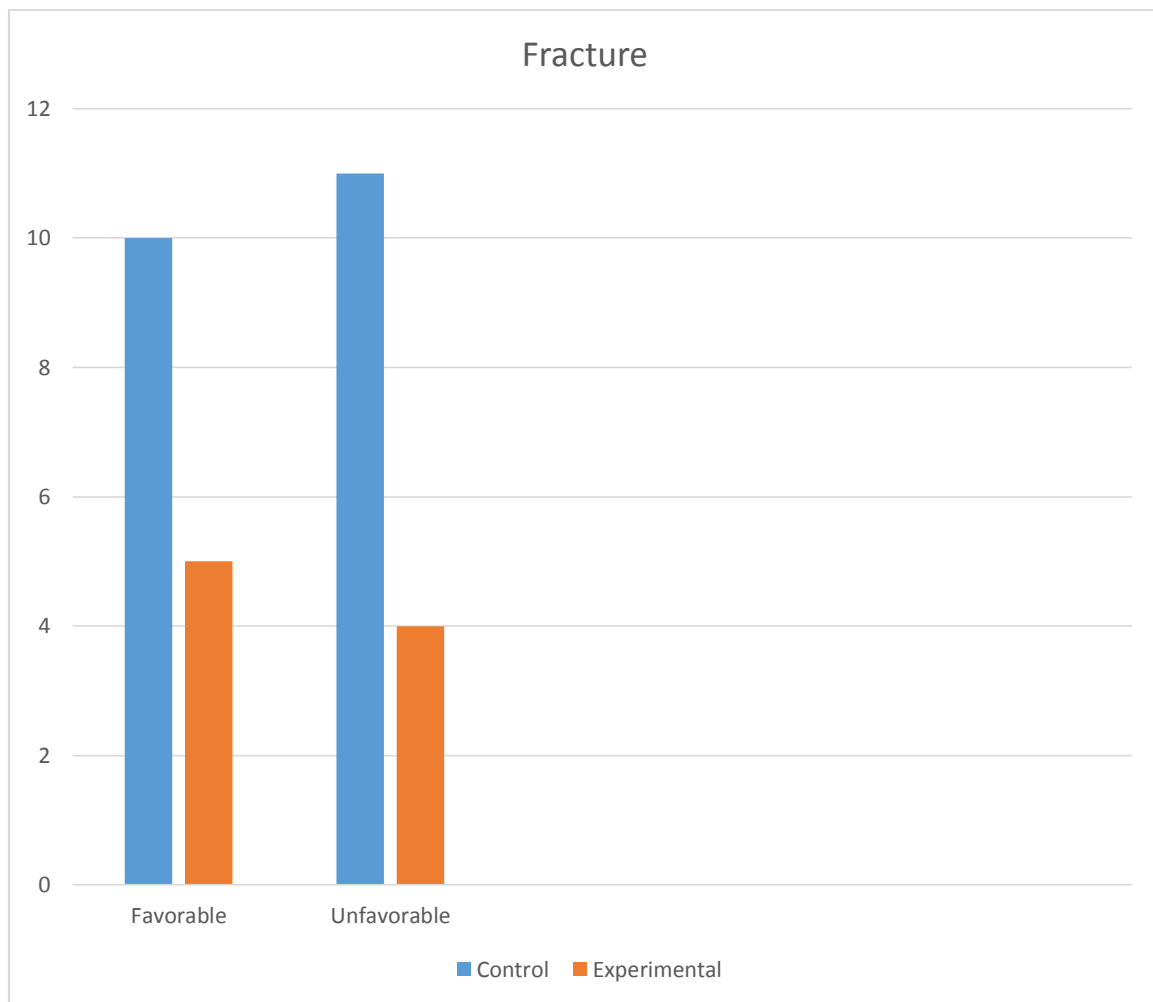


Chart 7 – Location of Fracture Site

8. Favorable / Unfavorable Fractures

In both the groups whether or not the fracture was favorable was taken into account and the results were tabulated. A p value co-efficient lesser than 0.05 was considered significant. In the control group 66.7 % of cases were favorable fractures (n = 10) and 33.3 % of cases were unfavorable fractures (n = 5). In the experimental group 71.5 % of cases were favorable fractures (n = 11) and 28.5 % of cases were unfavorable fractures (n = 4). Fisher's exact test was used for statistical purposes.

Group	Fracture		Total	p-Value
	Favorable	Unfavorable		
Control	10	5	15	1.000*
Experimental	11	4	15	
Total	21	9	30	

Table 3 – Favorable / Unfavorable Fracture**Chart 8 – Favorable / Unfavorable Fractures**

9. Approach

Some cases in this study were operated using an intra oral approach and some cases were operated using an extra oral approach. Fisher's exact test was used for statistical purposes.

Group	Approach		Total	P -Value
	Intra Oral	Extra Oral		
Control	11	4	15	0.651*
Experimental	13	2	15	
Total	24	6	30	

Table 4 – Approach

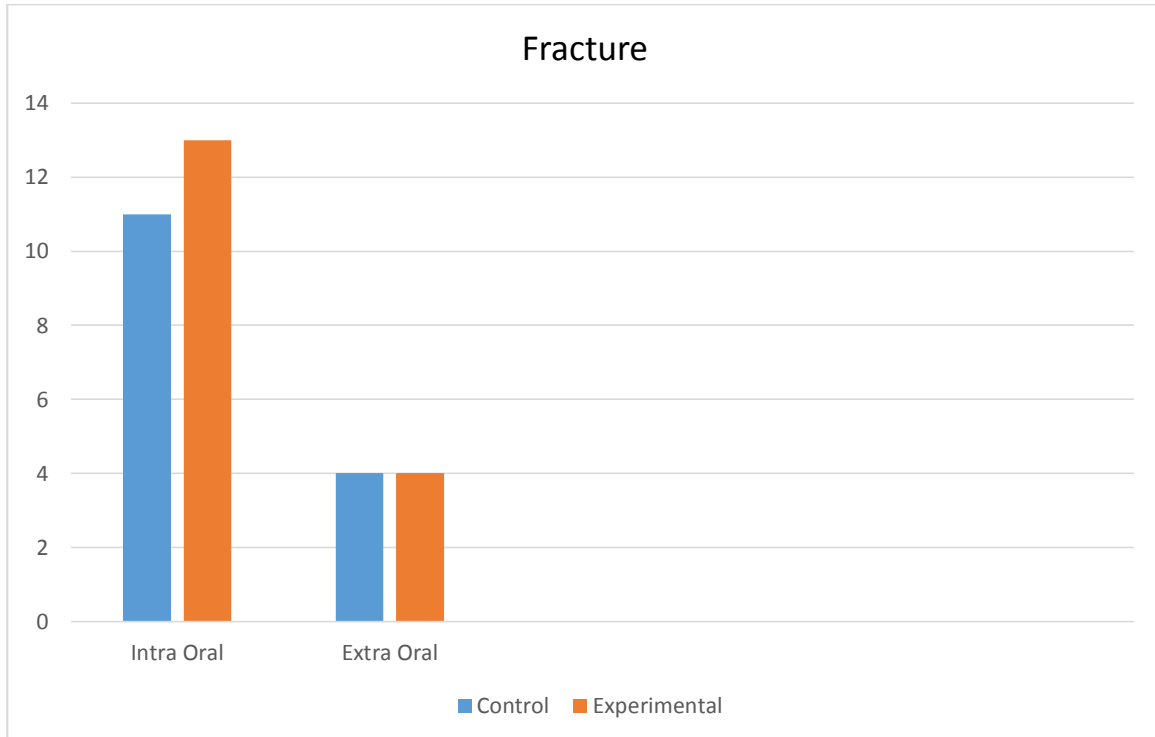


Chart 9 – Approach

10. Time from Injury – Surgery

The time taken for the patient from the accident till the start of the surgery was calculated. In the control group the mean time was 118. 33 hours with a standard deviation of 62. 55 hours. In the experimental group, the mean time was 168. 60 hours with a standard deviation of 100. 09 hours.

11. Intra Operative Time

Intra operative time in this study was calculated as the time from the incision till the time the last suture was completed. In the control group the mean intra operative time was 108. 13 minutes with a standard deviation of 28. 83 minutes. In the experimental group the mean intra operative time was 85. 67 minutes with a standard deviation. Hence, the experimental group had significantly reduced intra operative times. This factor is in favor of the experimental group.

12. Hardware Cost

The total cost of the plates and the screws was recorded in this study and it was tabulated. In the control group the mean cost of the hardware used for the surgery was around Rs. 4,668. 13 with a standard deviation of Rs. 1883. 11. In the experimental group the mean cost of the hardware was around Rs. 3,113. 33 with a standard deviation of Rs. 776. 08. These parameters show that there is a significant difference in the cost of the hardware used for both groups. This parameter is in favor of the experimental group.

13. Pre Operative & Post Operative Pain

The presence and the severity of pain was calculated pre operatively and post operatively at the given time intervals was calculated to determine any changes in the perception and the

severity of pain between the groups. The pain was calculated using a ten point VAS scale and the results were documented as follows.

	Pre Operative	1 st Post Operative Day	1 st Post Operative Week	1 st Post Operative Month	3 rd Post Operative Month	6 th Post Operative Month
Mean	6.67	7.53	6.40	3.80	1.87	.73
Median	7.00	8.00	6.00	4.00	2.00	.00
Std. Deviation	1.397	.990	.986	1.265	1.598	1.387

Table 5 – Pain Control Group

	Pre Operative	1 st Post Operative Day	1 st Post Operative Week	1 st Post Operative Month	3 rd Post Operative Month	6 th Post Operative Month
Mean	6.07	6.73	5.00	2.73	1.20	.13
Median	6.00	7.00	5.00	3.00	1.00	.00
Std. Deviation	1.438	.961	1.069	1.100	.414	.352

Table 6 – Pain Experimental Group

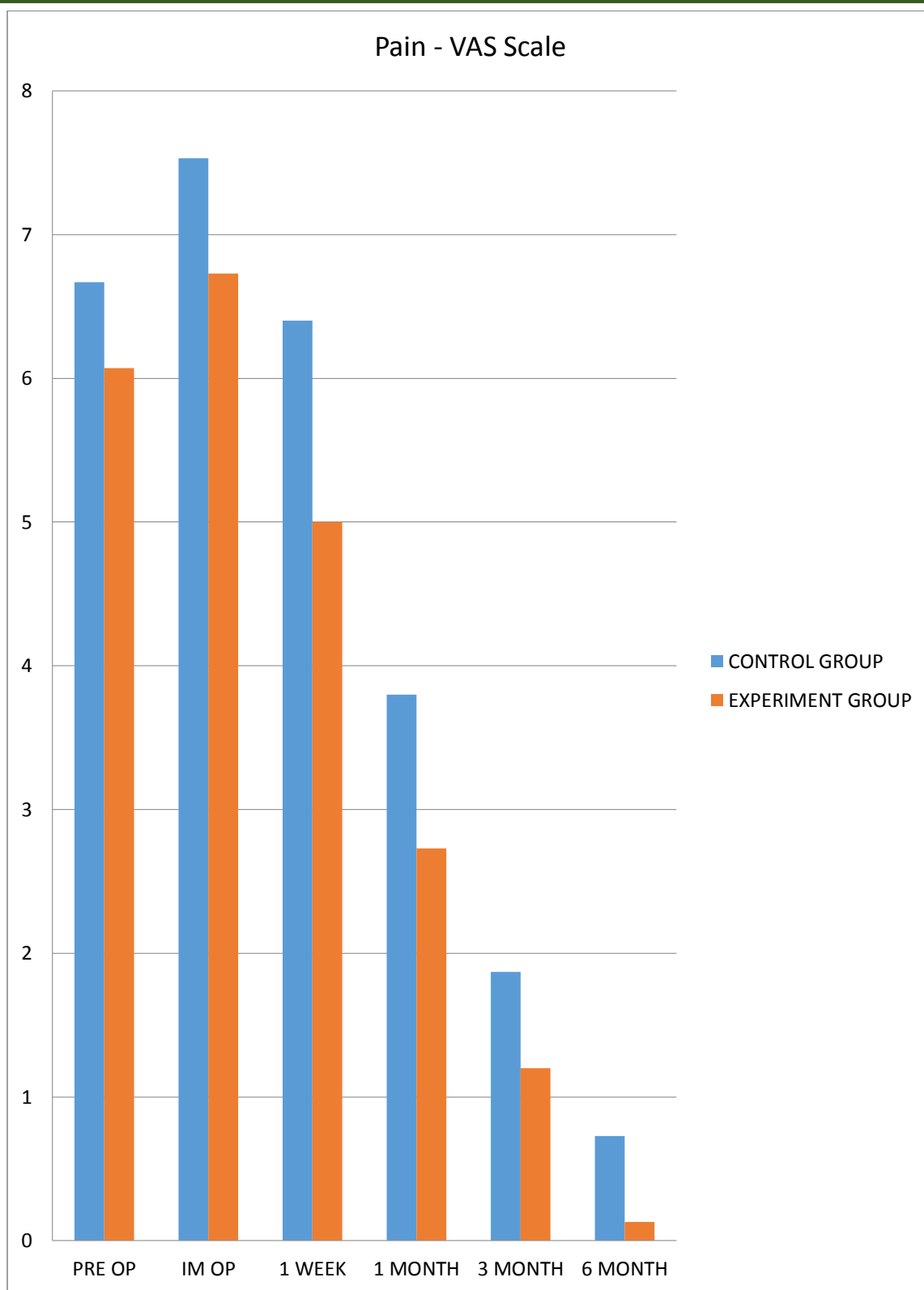


Chart 10 – Pain (10 Point VAS Scale)

The pain scores in each group were compared to each other to find whether there was any statistical significance in the two groups using the Mann Whitney U Test. The results are tabulated as below.

	Group	Mean Rank	P Value
Pre Operative	Control	16.90	0.372*
	Experimental	14.10	
1 st Post Operative Day	Control	18.83	0.031*
	Experimental	12.17	
1 st Post Operative Week	Control	20.87	0.000*
	Experimental	10.13	
1 st Post Operative Month	Control	18.80	0.041*
	Experimental	12.20	
3 rd Post Operative Month	Control	17.20	0.305*
	Experimental	13.80	
6 th Post Operative Month	Control	17.13	0.325*
	Experimental	13.87	

Table 7 – Comparison of Pain between Control & Experimental Group

It was noted that there was a statistically significant difference in pain perceived between the control and the experimental group at the 1st Post Operative Day, 1st Post Operative Week and the 1st Post Operative month. The intensity of pain perceived is less in the experiment group at these three time points, compared to the control group.

14. Mouth Opening

The maximum mouth opening was calculated pre operatively and post operatively.

	Pre Operative	1 st Post Operative Day	1 st Post Operative Week	1 st Post Operative Month	3 rd Post Operative Month	6 th Post Operative Month
Mean	28.73	21.20	26.47	33.93	36.93	40.07
Median	27.00	21.00	25.00	34.00	37.00	42.00
Std. Deviation	5.663	6.097	5.263	3.283	3.535	6.745

Table 8 – Mouth Opening Control Group

	Pre Operative	1 st Post Operative Day	1 st Post Operative Week	1 st Post Operative Month	3 rd Post Operative Month	6 th Post Operative Month
Mean	33.67	25.20	31.67	37.20	41.67	44.80
Median	33.00	25.00	32.00	38.00	42.00	45.00
Std. Deviation	2.992	4.057	3.716	2.808	2.690	2.111

Table 9 – Mouth Opening Experimental Group

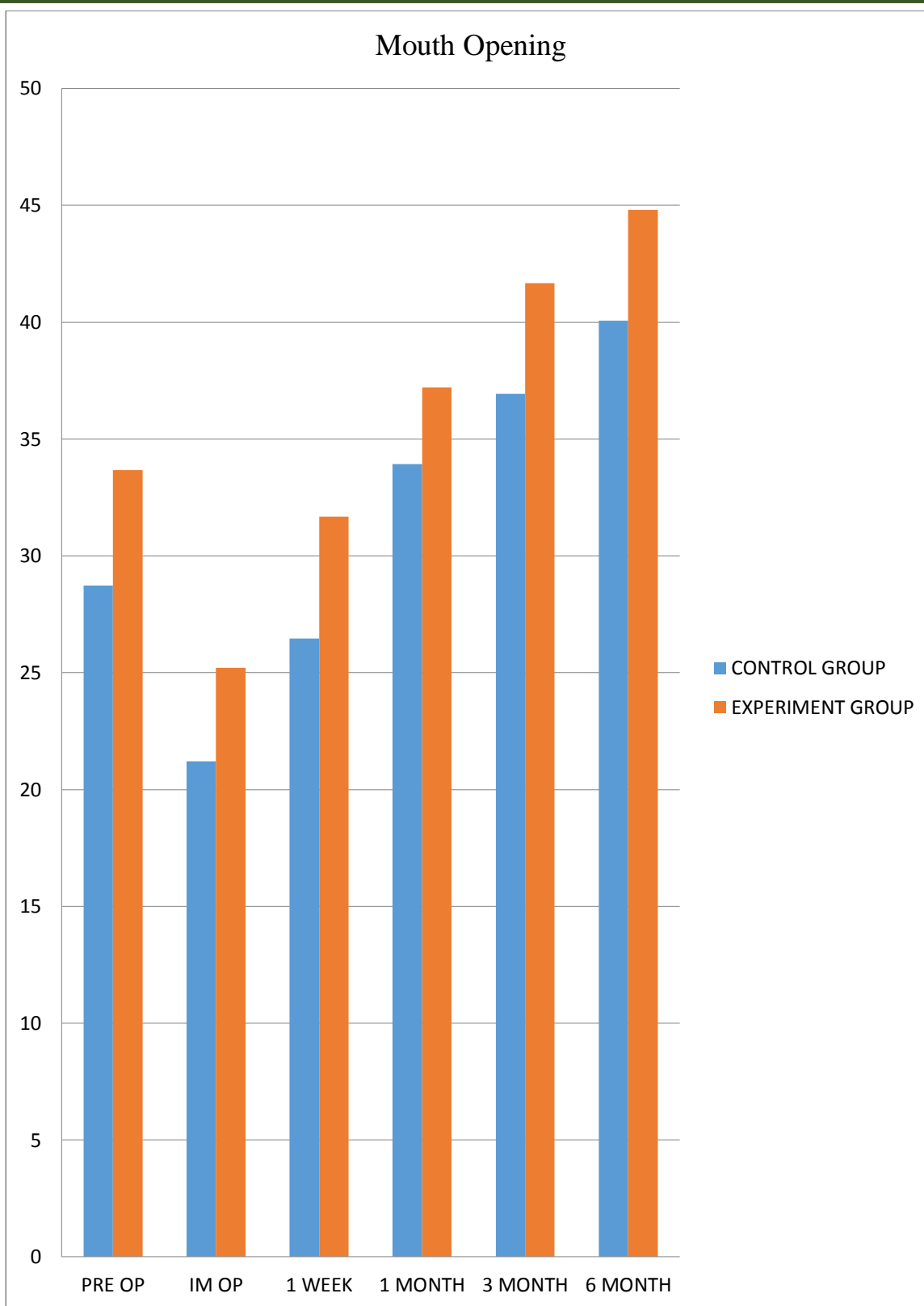


Chart 11 – Mouth Opening

The maximum mouth opening in each group were compared to each other to find whether there was any statistical significance in the two groups using the Mann Whitney U Test. The results are tabulated as below.

	Group	Mean Rank	P Value
Pre Operative	Control	11.37	0.010*
	Experimental	19.63	
1 st Post Operative Day	Control	12.50	0.061*
	Experimental	18.50	
1 st Post Operative Week	Control	11.00	0.004*
	Experimental	20.00	
1 st Post Operative Month	Control	11.23	0.007*
	Experimental	19.77	
3 rd Post Operative Month	Control	10.07	0.000*
	Experimental	20.93	
6 th Post Operative Month	Control	11.70	0.016*
	Experimental	19.30	

Table 10 – Mouth Opening Control & Experimental Group

There was statistically significant difference in the mouth opening between control and experiment group at all time points except at the 1st post operative day. The mouth opening was more in the experiment group compared to the control group.

15. Occlusion

Occlusion was noted pre operatively and post operatively.

Time Periods		Control Group	Experimental Group	P - Value
Pre Operative	Normal	3	11	0.009*
	Abnormal	12	4	
1 st Post Operative Day	Normal	11	11	1.000*
	Abnormal	4	4	
1 st Post Operative Week	Normal	11	12	1.000*
	Abnormal	4	3	
1 st Post Operative Month	Normal	12	12	1.000*
	Abnormal	3	3	
3 rd Post Operative Month	Normal	13	15	0.483*
	Abnormal	2	0	
6 th Post Operative Month	Normal	13	15	0.483*
	Abnormal	2	0	

Table 11 – Occlusion

There was statistically significant difference in occlusion between the two groups only pre-operatively. At other time points, there was no statistically significant difference.

16. Wound Healing

Wound healing was evaluated post operatively at the given time intervals.. The statistical significance was evaluated using the Fisher's Exact Test.

Time Periods		Control Group	Experimental Group	P - Value
1 st Post Operative Day	Normal	13	15	1.000*
	Abnormal	2	0	
1 st Post Operative Week	Normal	11	13	1.000*
	Abnormal	4	2	
1 st Post Operative Month	Normal	11	13	1.000*
	Abnormal	2	2	
3 rd Post Operative Month	Normal	2	0	0.483*
	Abnormal	13	15	
6 th Post Operative Month	Normal	2	0	0.483*
	Abnormal	13	15	

Table 12 – Wound Healing

There was no statistically significant difference in between the control and the experimental group when the parameter of wound healing was evaluated.

17. Infection

The presence or absence of infection was documented in both the groups. Fisher's Exact Test was used for statistical purposes.

Time Periods		Control Group	Experimental Group	P - Value
1 st Post Operative Day	Absent	15	15	--
	Present	0	0	
1 st Post Operative Week	Absent	15	15	--
	Present	0	0	
1 st Post Operative Month	Absent	11	13	0.651*
	Present	4	2	
3 rd Post Operative Month	Absent	11	13	0.651*
	Present	4	2	
6 th Post Operative Month	Absent	11	15	0.100*
	Present	4	0	

Table 13 – Infection

There was no significant difference in the presence of infection in the control and the experimental group indicating that there was no major statistical difference in between the two groups when the parameter of presence of absence of infection was evaluated.

18. Segmental Mobility

Segmental Mobility of the fractured segments was documented in both the groups

Time Periods		Control Group	Experimental Group	P - Value
Pre Operative	Absent	3	5	0.682*
	Present	12	10	
1 st Post Operative Day	Absent	3	12	0.003*
	Present	12	3	
1 st Post Operative Week	Absent	9	13	0.215*
	Present	6	2	
1 st Post Operative Month	Absent	10	15	0.042*
	Present	5	0	
3 rd Post Operative Month	Absent	13	15	0.483*
	Present	2	0	
6 th Post Operative Month	Absent	15	15	
	Present	0	0	

Table 14 – Segmental Mobility

There was a statistically significant difference in between the groups at the 1st post operative day and 1st post operative month.

19. Plate Exposure

The presence or absence of plate exposure was documented in both the groups. Fisher's Exact Test was used for statistical purposes.

Time Periods		Control Group	Experimental Group	P - Value
1 st Post Operative Day	Absent	15	15	--
	Present	0	0	
1 st Post Operative Week	Absent	15	15	--
	Present	0	0	
1 st Post Operative Month	Absent	13	13	1.000*
	Present	2	2	
3 rd Post Operative Month	Absent	13	15	0.483*
	Present	2	0	
6 th Post Operative Month	Absent	13	15	0.483*
	Present	2	0	

Table 15 – Plate Exposure

There was no significant difference in plate exposure in between the control and the experimental groups.

20. Paresthesia

Paresthesia was documented in both the groups.

Time Periods		Control Group	Experimental Group	P - Value
Pre Operative	Absent	8	11	0.450*
	Present	7	4	
1 st Post Operative Day	Absent	5	10	0.143*
	Present	10	5	
1 st Post Operative Week	Absent	9	12	0.427*
	Present	6	3	
1 st Post Operative Month	Absent	12	13	1.000*
	Present	3	2	
3 rd Post Operative Month	Absent	12	15	0.224*
	Present	3	0	
6 th Post Operative Month	Absent	13	15	0.483*
	Present	2	0	

Table 16 – Paresthesia

There was no statistically significant difference between the two groups.

21. Reduction of Fractured Segments

The reduction of fractured segments was assessed during the surgery after the fixation had been completed and it was concluded that both conventional and experimental mini plates provided adequate reduction of fractured segments.

In a developing country like India, exposure to trauma due to various reasons is increasing day by day. The incidences of injuries to the facial skeleton have alarmingly increased due to the rapid emergence of many high speed automobiles and gradual increase in incidences of interpersonal violence (70). Amongst all the bones of the facial skeleton, the mandible is highly susceptible to traumatic injuries (10). Disfigurement of the face becomes a serious cause of concern making the surgical treatment of fractured facial skeleton an essential part to restore the function and aesthetics. The treatment of the facial fractures have evolved over a period of time from methods like splinting and bandaging which resemble the closed reduction of recent times. With the introduction to open reduction and rigid internal fixation over the past 30years and its increasing popularity has brought numerous advances in the management of fractures of the mandible (71).

The organized research done by the AO group has recommended open osteosynthesis for maxillofacial region; the original management objectives were the most important advantages of this technique (71). The objectives were

1. Early, active, pain free mobilization of the jaws
2. Avoidance of IMF
3. Safe and secured airways without tracheostomies particularly in polytrauma patients
4. Shorter periods of hospitalization.

These were at first represented as the fundamentals of good internal fixation. However, with increased understanding of the importance of soft tissues, the biomechanics of fixation and the fracture healing resulted in certain conceptual changes in the management of fracture mandible. The rigid fixation with dynamic compression osteosynthesis is an alternative method for the treatment of facial fractures without maxillomandibular fixation (72). This leads to rapid wound

healing without callus formation. However, the main disadvantages associated with this technique were :

1. Wide extra oral incision causing risk of damage to the marginal mandibular branch of the facial nerve.
2. Postoperative scar formation.
3. Bicortical screw engagement due to the bulky nature of the plates causing sensitivity.
4. Uneven compression by the plate which may lead to necrosis of bone
5. Not applicable in comminuted fractures and
6. Requirement of second surgery for plate removal.

Later anatomical and biomechanical studies done by Champy et al had proven that under physiological strain there were forces of tension produced along the alveolar border and forces of compression along the lower border of the mandible (27). The traction strains were found to be injurious and had to be neutralized. At the level of body of the mandible these forces were found to produce moments of flexion predominantly, which are found to be strongest towards the angle and weakest in the premolar region. In the anterior part of the mandible anterior to the canines, these forces produced predominantly torsional moments that increase in strength towards the midline. Therefore the principles of osteosynthesis were modified according to the mechanical qualities of the mandible, taking into account the anatomical variations in the mandible. This supports the fact that monocortical fixation alone is sufficient in the mandibular fractures as the osteosynthesis by plates and screws on the outer cortical plate is solid enough to support the strains developed by the masticatory muscles. Champy et al also recommended that the compression of the fragments was no longer advisable because there existed a natural strain of compression along the lower border of mandible due to the masticatory forces. Based on these observations, Champy

et al suggested the ideal lines of osteosynthesis. According to this, by placing the plate at the most biomechanically favorable site the thickness of the plate can be kept to a minimum with the consequent advantage of increased malleability of the plates. Hence miniplates have replaced compression plates for bone fixation in the Maxillomandibular region as they are

1. Small and easy to adapt.
2. Mono cortical application.
3. Intra oral approach
4. Functional stability
5. Bio mechanical favorability
6. No need for second surgery.
7. Less skin sensitivity.

The initial biomaterials available for mini plates were vitalium (cobalt based alloy) later the more successful material stainless steel was used (24). The current decade has seen another material called as titanium which has superior mechanical properties than other materials used till date. The advent of titanium soon replaced stainless steel allowing surgeons to use smaller mini plates (less than 1 mm) for rigid internal fixation of fractures of the mandible. But the mini plates also have some inherent disadvantages mainly due to their design (45,56). They are

1. Conventional bone plate/screw systems require precise adaptation of the plate to the underlying bone, without this intimate contact, tightening of the screw will draw the bone segments toward the plate, resulting in alterations in the position of the osseous segments and the occlusal relationship
2. In conventional bone plate/screw systems stability of the fracture segments is achieved by the friction between the bone and the screw interface only. If the screw is placed along the

fracture line there may be absence of bone present around the screw leading to screw loosening. This may lead to inflammatory response and subsequent chances of infection

To overcome these disadvantages a new type of plating system was developed which has a locking system in between screw and the plate also called as locking screw/ plate system . These plates achieve stability by locking the screw onto the plate and have been shown to enhance fixation stability, as the screws are unlikely to loosen from the plate (43). This means that, even if the screw is inserted into the fracture line, loosening of the screw will not occur. The possible advantage to this property of the locking plate/screw system decreased incidence of inflammatory complications from loosening of hardware. Here the screw, plate and the bone act as a single functional unit acting as a mini internal fixator, which transmits the functional forces to the bone thereby dissipating the forces. In the case of conventional mini plates there may be concentration of functional forces around the screw and bone interface leading to possible release of inflammatory response and subsequent bone resorption around the screws leading to screw loosening. Another unique and probable theoretical advantage to the locking plate/screw system is that it becomes unnecessary for the plate to have intimate contact with the underlying bone making plate adaptation easier leading to lesser alterations in the alignment of the segments and changes in the occlusal relationship upon screw Tightening (43). It is observed that the degree of plate adaptation affected the mechanical behavior of non-locking plates but did not affect the locking plate/screw system. The third advantage in the locking plate/screw system is that they do not disrupt the underlying cortical bone perfusion as much as the conventional plates which compress the undersurface of the bone plate to the cortical bone (45,56). It is also proposed that this system provides greater stability than does the standard conventional miniplates and also in bony pathologies like osteoporosis and other age related bony changes locking plate system

provides better stability across fracture segments. The only exception is that one should use a drill guide to “center” the drill hole within the center of bone plate to facilitate proper screw locking to the plate. The screws, plate and bone form a solid framework with higher stability than the traditional miniplate system. The locking plate/screw system has demonstrated higher stability across a fracture/osteotomy gap compared with the conventional non-locking 2.0 mm miniplate in in-vitro studies (12,15,17,18,41,43,45,51,52,63,64).

The current study was undertaken to evaluate the outcome and results in the treatment of 30 mandibular fractures with 2.0 mm titanium locking miniplates fixed and self-threading monocortical screws in all the patients. Similar kind of titanium miniplates were used by Marisa Gabrielli et al (16).

Several studies have shown variation in prevalence of gender in relation to incidence of fracture of the mandible. With most of them are associated with male predominance (10,73–75). Results in the study showed that 90% of the cases of maxillofacial fractures occurred in male patients and 10% in female patients. The mean age was 30.41 and 32.45 years in the control and the experimental group respectively. These figures were similar to the study done by Marisa Gabrielli et al who reported incidence of 79.06% in males with a mean age of 30.3 years (16).

Many factors are considered responsible for the incidence of maxillofacial trauma. Ellis et al showed that the assaults to be the first cause for fractures followed by motor vehicle accidents and falls, another study done by Jose -Moreno et al encountered 43.1% fractures due to road traffic accidents and 35.8% due to assaults (72). Marisa Gabrielli et al also concluded the same findings (16). The study conducted by us showed road traffic accidents in 27 patients as the main cause of mandibular fractures followed by accidental fall in 1 patients and domestic violence in 2 patients.

In studies conducted by Verma et al and Jose Moreno et al 43.2 % & 39.2% fractures occurred at parasymphysis region (37). In this study majority of the fractures occurred at the Parasymphysis region.

The main parameters considered and seen for pre-operative clinical evaluation were signs of displacement, soft tissue injury, edema, paresthesia, deranged occlusion, step deformity and inability to open the mouth. Radiographic evaluation was done with panoramic and PNS radiographs. Parameters considered for post-operative clinical evaluation were signs of infection, mobility of the fracture fragments, occlusal disturbances and paresthesia. All cases were evaluated at the 1st post-operative day, 1st post-operative week, 1st post-operative month, 3rd post-operative month and the 6th post-operative month. Postoperative evaluation showed that there were no cases of fibrous union, malunion or nonunion detected clinically. Plate removal was done in one case postoperatively after 8 months. Post-operative radiographs showed adequate fixation of fracture segments without any signs of non-union or infection in all the patients (100%). At the end of the 1st month, the anatomic reduction of the treated fractures was evident without any signs of step defect or gap formation at the two fractured ends. The blending of margins and trabecular bone formation was indistinguishable at the end of 3rd month, showing new bone formation radiographically. Blending of margins showed a gradual increase from the 1st month to the 3rd month. Hardware impingement over the inferior alveolar nerve is not seen in any of the cases radiographically. Assessment of the involved nerve for paresthesia was done by subjective and objective testing. Hypoesthesia / paresthesia of mucosa in the mental region or lower lip were observed. Postoperatively 3 patients had paresthesia after 1 month which subsided by the 3rd month. Neurosensory alterations were noted through objective testing and were more frequently related with fracture of the parasymphysis region.

Infections are some of the most troublesome complications to occur, however, it is very difficult to compare such data because the methods of treatment were different with associated compromised conditions. The results in this study are comparatively better than other studies of Verma et al who showed 13.6% of postoperative infection in non-locking group and 4.7% in locking group (64). The complications observed in this preliminary study of 30 patients were minimal which showed 100% success rate in this plating system.

Jose Moreno et al concluded that the occurrence of complications in mandibular fractures is fundamentally related to the direction, degree, magnitude of the force and severity of the fracture rather than to the type of fixation used (37). In this study the use of 2.0 mm titanium locking plates and screws showed good intra operative handling adequate clinical stability with follow up of 6 months showing good soft tissue healing. These results show similarity with the study of Samrat Sabhlok et al (60).

The stability of the fractured fragments was good and found to be reliable and effective intraoperatively. Chandan Prabhakar et al concluded that the locking miniplates system was found to be reliable and effective in management of mandibular fractures without postoperative intermaxillary fixation (65). In this study the use of 2.0 mm titanium locking plate system showed increased stability and shorter surgical time. A similar study was done by Sauerbier et al in which the use of 2.0 mm locking plate system with its advantages of improved handling characteristics, increased stability, shorter surgical time and the preservation of bony perfusion were proven (61). Hence it is a viable alternative to conventional miniplates in the management of mandibular fractures.

The requirement of plate removal is very low in this study. This is comparatively same as the study done by J. O Connell et al a low removal rate of 3% suggests that the removal of asymptomatic titanium miniplates is not indicated (57).

The use of 2.0 mm titanium locking miniplates system was found to be simple and not requiring the plate to be compressed to the bone to provide stability. This is comparatively same with the study done by Allan S Herford and Edward Ellis (35).

In the present study, a sincere attempt has been made to clinically evaluate the efficacy of 2.0 mm titanium locking plate/screw system in the management of mandibular trauma and the results of this study are in accordance with the study conducted by different authors.

In order to achieve better fixation, increased stability and early return to function while treating minimally displaced or undisplaced maxillofacial fractures various techniques and biomaterials have evolved in the past. The present study was conducted to evaluate the efficacy of 2.0 mm titanium locking miniplates in the management of mandibular trauma. Thirty cases reporting to the Department of Oral & Maxillofacial Surgery, Adhiparasakthi Dental College & Hospital, Melmaruvathur presenting with mandibular fractures requiring open reduction and internal fixation were selected for the study. In the titanium locking plate and screw system, the screw locks not only to the bone but also to the bone plate. This is accomplished by having a screw with a double thread. One thread will engage the bone; another will engage a threaded area of the bone plate. The result is a locking titanium plate system which in effect provides a mini-internal fixator, since the plate locks to the screw rather than gaining its rigidity by being compressed against the bone.

The study observed that locking plates/screw system offers significant advantages over conventional plates & screws.

- Less screw loosening
- Greater stability across the fracture site
- Less precision required in plate adaptation
- Less alteration in osseous or occlusal relationship upon screw tightening.

In all the thirty cases satisfactory occlusion and anatomic reduction achieved intraoperatively. The operating time is considerably reduced since accurate adaptation to the underlying bone is not required in this system and also because only plate is used for the reduction of a fracture. Post-operative complications were reported in 1 fracture out of 30 fractures. One minor complication was plate exposure which required removal of the plate.

The stability achieved by this system is satisfactory and can be used in all mandibular fractures.

We would like to conclude that the use of 2.0 mm titanium locking miniplates/screw system was found to be advantageous with adequate stability post-operatively. However the use of this system does not eliminate postoperative complications.

As we did not encounter any cases with bony pathologies during our study course, we recommend further studies for fixation of fractures in more number of patients with the locking plate design in geriatric and patients with bony pathologies.

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Picture 2 - Pre Operative – Intra Oral Photograph

Experimental Group



Picture 1 - Pre Operative – Extra Oral Photographs



Picture 2 - Pre Operative – Intra Oral Photograph



Picture 3 - Pre Operative Radiograph



Picture 4 – Intra Operative Photos



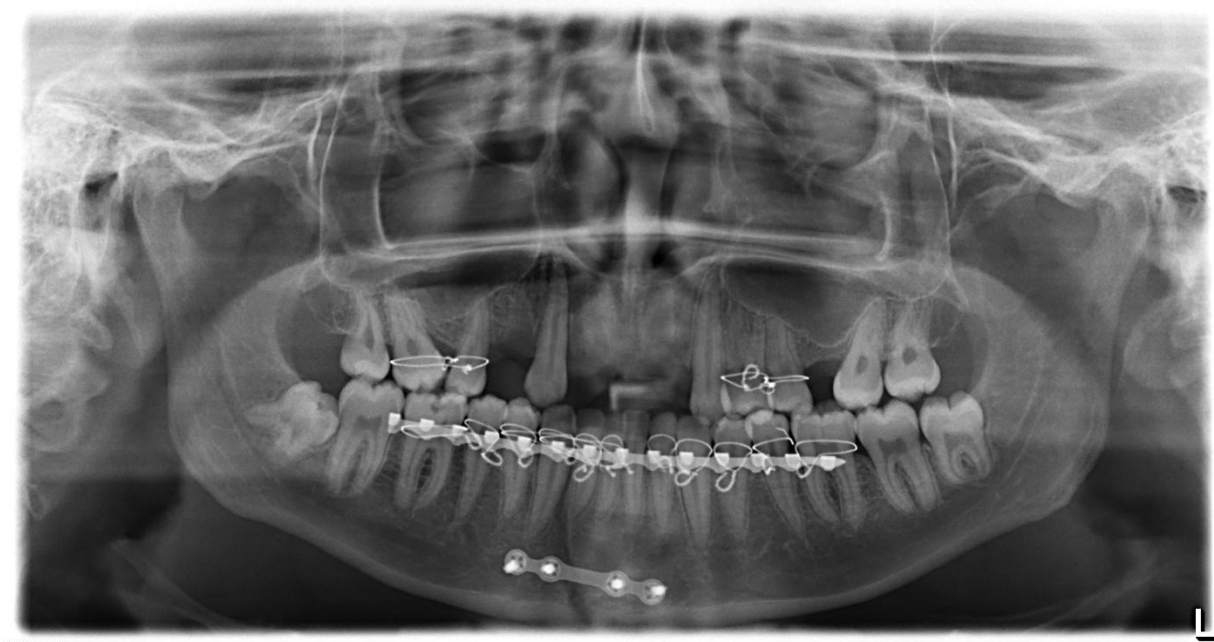
Picture 5 – Post Operative – Extra Oral Photographs



Picture 6 - Post Operative – Intra Oral Photograph



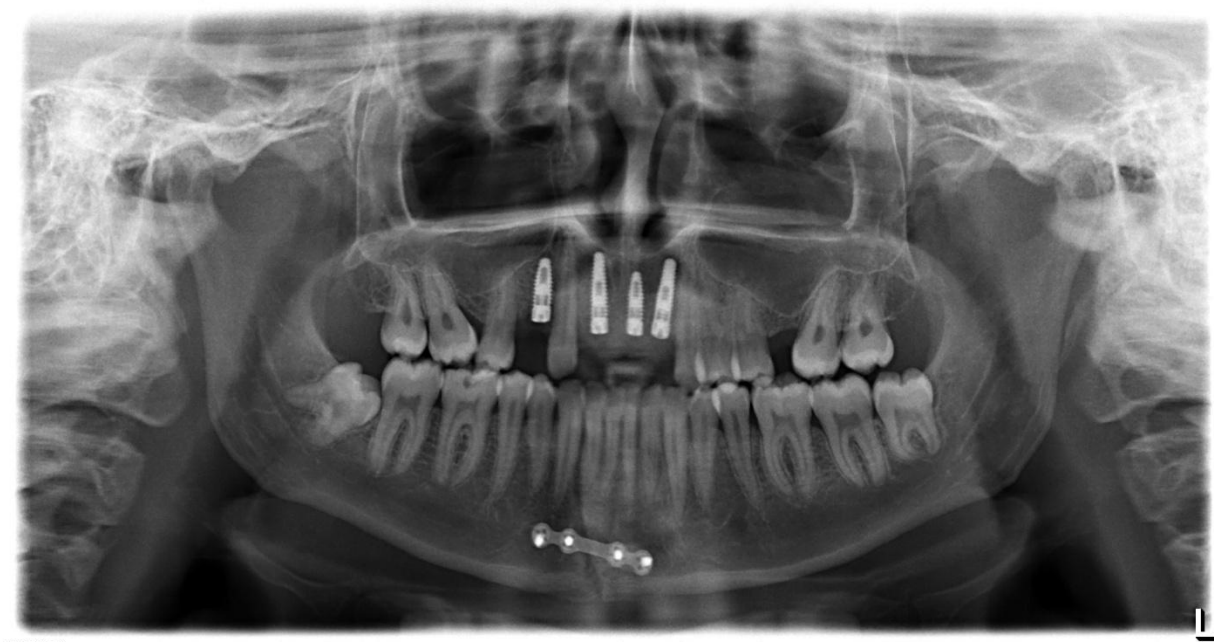
Picture 7 - Post Operative – Radiograph (1st Post Operative Day)



Picture 8 - Post Operative – Radiograph (1st Post Operative Week)



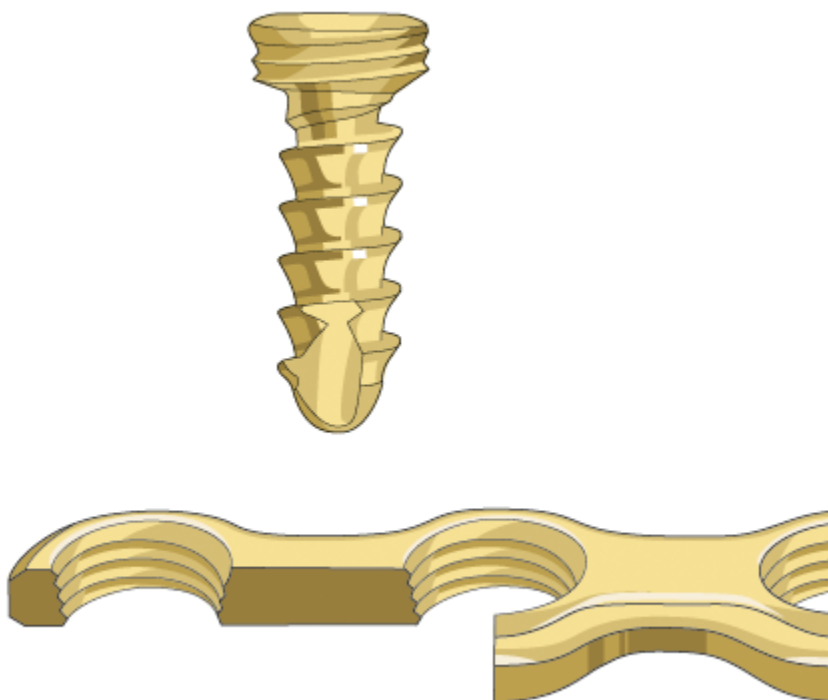
Picture 9 - Post Operative – Radiograph (1st Post Operative Month)



Picture 10 - Post Operative – Radiograph (3rd Post Operative Month)

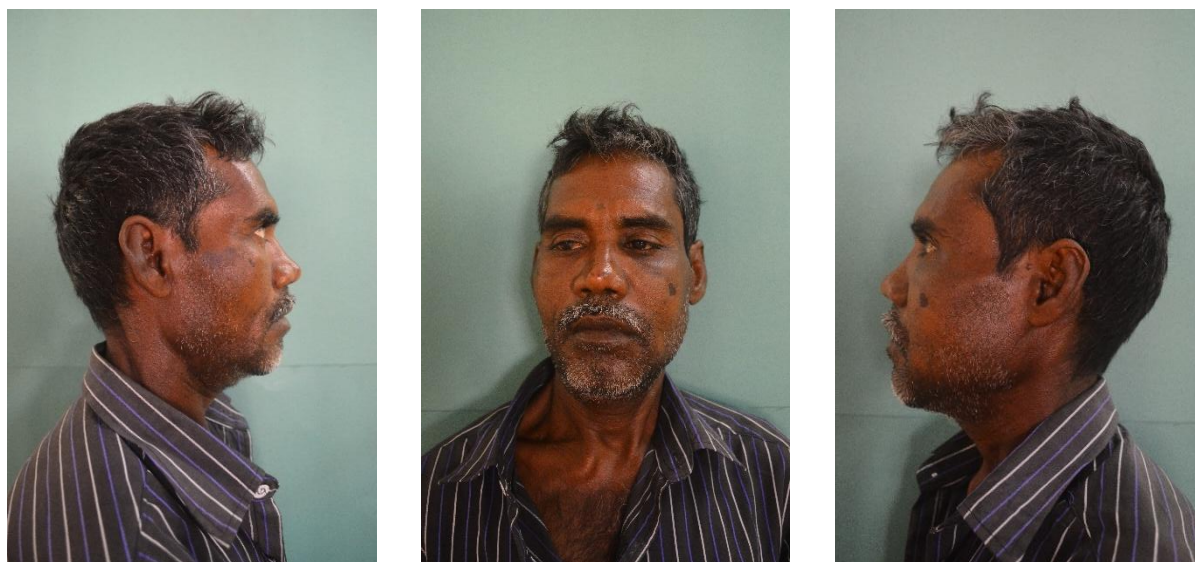


Picture 11 - Post Operative – Radiograph (6th Post Operative Month)



Picture 12 – Locking Plates & Screws

Control Group



Picture 13 - Pre Operative – Extra Oral Photographs



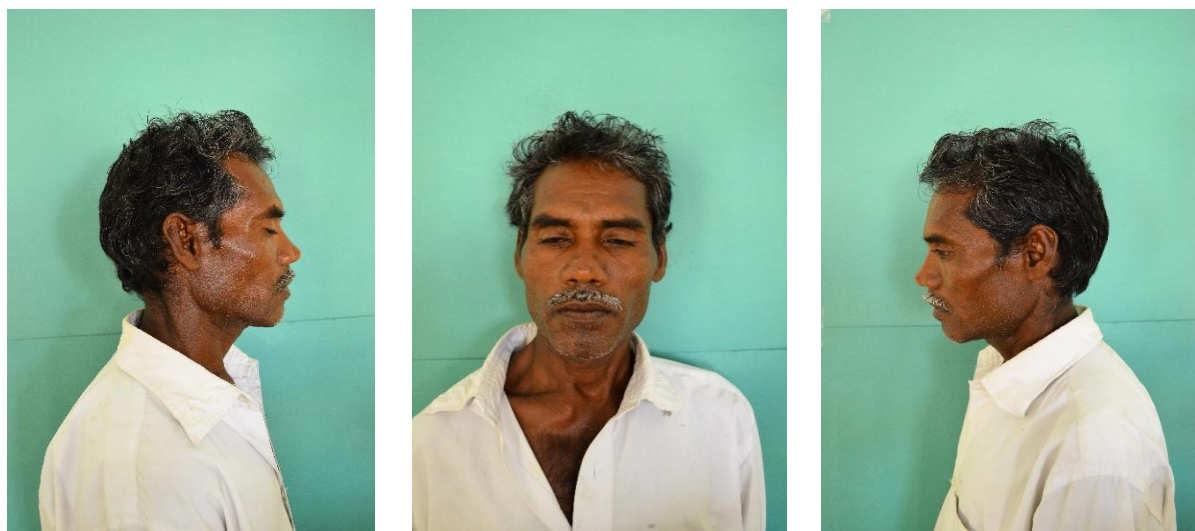
Picture 14 - Pre Operative – Intra Oral Photographs



Picture 15 - Pre Operative Radiograph



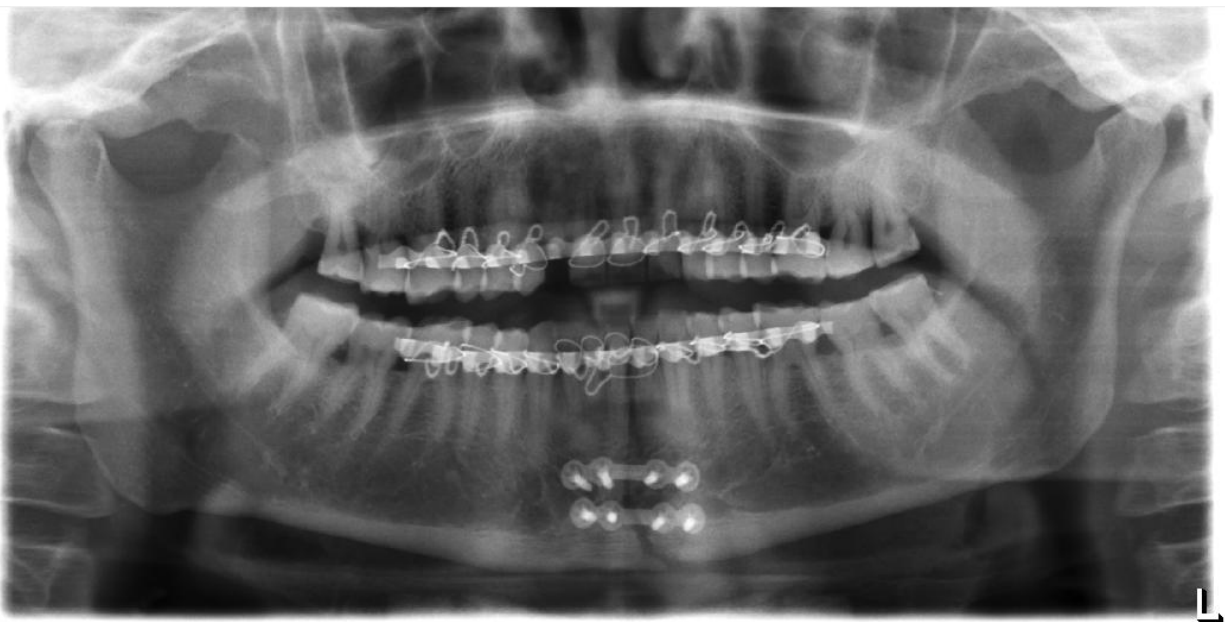
Picture 16 – Intra Operative Photographs



Picture 17 - Post Operative – Extra Oral Photographs



Picture 18 - Post Operative – Intra Oral Photograph



Picture 19 - Post Operative Radiograph (1st Post Operative Day)



Picture 20 - Post Operative Radiograph (1st Post Operative Week)



Picture 21 - Post Operative Radiograph (1st Post Operative Month)



Picture 22 - Post Operative Radiograph (3rd Post Operative Month)



Picture 23 - Post Operative Radiograph (6th Post Operative Month)



Picture 24 – Conventional Miniplates & Screws



Picture 25 – Armamentarium

Maxillofacial Trauma Case Sheet

NAME		DATE	
OP NO		AGE	
ADDRESS		SEX	
		DATE OF BIRTH	
		OCCUPATION	
		S / M / W	

CHIEF COMPLAINT
HISTORY OF PRESENTING ILLNESS
PAST MEDICAL HISTORY
PAST SURGICAL HISTORY
PAST DENTAL HISTORY
PERSONAL HISTORY
FAMILY HISTORY

GENERAL EXAMINATION	
Temperature	
Blood Pressure	
Pulse	
Respiratory Rate	
Gait	
Orientation	
Build	
Nourishment	
Pallor	
Cyanosis	
Icterus	

Clubbing	
Pedal Edema	
General Lymphadenopathy	
Others	

GLASGOW COMA SCALE		
BEHAVIOUR	RESPONSE	SCORE
Eye Opening Response	Spontaneously	4
	To Speech	3
	To Pain	2
	To Response	1
Best Verbal Response	Oriented to Time, Place & Person	5
	Confused	4
	Inappropriate Words	3
	Incomprehensible Words	2
	No Response	1
Best Motor Response	Obeys Commands	6
	Moves to Localized Pain	5
	Flexion Withdrawal From Pain	4
	Abnormal Flexion	3
	Abnormal Extension	2
	No Response	1
Score		
Interpretation		
Others		

CRANIAL NERVES			
NUMBER	NERVE	RIGHT	LEFT
I			
II			
III			
IV			
V			
VI			
VII			
VIII			
IX			
X			
XI			
XII			
Others			

EXTRA ORAL EXAMINATION	
Hemorrhage	
Laceration	

Tissue Loss	
Abrasion	
Oedema	
Ecchymosis	
Contour Defects	
CSF Leak Nose / Ear	
Others	
HARD TISSUE EXAMINATION	
CRANIUM	
ORBITAL MARGINS	
NASAL BONES	
ZYGOMA	
CONDYLES	
MANDIBULAR BORDER	
COMPRESSION TEST	
MAXILLA	
OTHERS	

INTRA ORAL EXAMINATION									
Strike Out Missing Teeth Cross Out Teeth to be Extracted Encircle & Cross Out Teeth Recently Displaced Encircle Teeth Unsuitable for Splinting Indicate Roots With Cross Broken Teeth									
<table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%; text-align: center;">E D C B A</td> <td style="width: 50%; text-align: center;">A B C D E</td> </tr> <tr> <td style="text-align: center;">8 7 6 5 4 3 2 1</td> <td style="text-align: center;">1 2 3 4 5 6 7 8</td> </tr> <tr> <td style="border-top: 1px solid black; text-align: center;">8 7 6 5 4 3 2 1</td> <td style="border-top: 1px solid black; text-align: center;">1 2 3 4 5 6 7 8</td> </tr> <tr> <td style="text-align: center;">E D C B A</td> <td style="text-align: center;">A B C D E</td> </tr> </table>		E D C B A	A B C D E	8 7 6 5 4 3 2 1	1 2 3 4 5 6 7 8	8 7 6 5 4 3 2 1	1 2 3 4 5 6 7 8	E D C B A	A B C D E
E D C B A	A B C D E								
8 7 6 5 4 3 2 1	1 2 3 4 5 6 7 8								
8 7 6 5 4 3 2 1	1 2 3 4 5 6 7 8								
E D C B A	A B C D E								

OCCLUSION	
Present	
Prior to Accident	
OTHERS	

FRACTURE SITES	
Maxilla	

Mandible	
Other Facial Bones	
Other	

LACERATION / ECCHYMOSIS
OTHERS

RADIOGRAPHS
<input type="checkbox"/> IOPA
<input type="checkbox"/> OPG
<input type="checkbox"/> OCCLUSAL
<input type="checkbox"/> PNS
<input type="checkbox"/> SMV
<input type="checkbox"/> PA SKULL
<input type="checkbox"/> PA JAWS
<input type="checkbox"/> LATERAL SKULL
<input type="checkbox"/> OBLIQUE MANDIBLE
<input type="checkbox"/> CHEST X RAY
<input type="checkbox"/> CT SCAN
<input type="checkbox"/> Others

PROVISIONAL DIAGNOSIS

FINAL DIAGNOSIS

TREATMENT PLAN

Informed Consent

I _____ the undersigned hereby authorize Dr. _____ at Adhiparasakthi Dental College and Hospital to perform upon me the following procedure(s) for research purpose:

In this procedure, all the patients after pre-operative evaluation and obtaining the written informed consent, all the patients sustaining mandibular fractures which fall in the inclusion criteria will be included in the study. The above procedure along with the purpose of the study has been explained to me in detail in comprehensible terms. I have received appropriate response to all my doubts and clarifications. I understand that I may be exposed to radiation dose twice or more during the course of the study. I also understand that photographs will be taken in the course of the study and that the results generated from this study can be published in scientific literature, for which I do not have any objections. I have understood that I have the right to refuse my consent or withdraw it at any time during the study.

I understand that signing this consent form indicates that I voluntarily agree to participate in this study.

I confirm that I understand the information presented in this consent form.

Signature of Participant

Date :

Place :

Signature of Witness

Date :

Place :

Signature of the investigator 1

Date :

Place :

Signature of the investigator 2

Date :

Place :